In-Lab Training Manual

UniCel DxC Synchron
Access Clinical System
Integrated Workstations

For In Vitro Diagnostic Use

This manual is intended for
UniCel DxC 660i
UniCel DxC 680i
UniCel DxC 860i
UniCel DxC 880i
WARNINGS AND PRECAUTIONS

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate the instrument.

Beckman Coulter, Inc. urges its customers and employees to comply with all national health and safety standards such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, suitable laboratory attire when operating or maintaining this or any other automated laboratory equipment.

INTENTION FOR USE

This document is not intended to replace the information in your Instrument Instructions for Use Manual (IFU) or Help System. Information in the Instructions for Use Manual or Help System supersedes information in any other manual.

REVISION STATUS

Rev. A (June 2014)
Based on DxC software version 5.4 and DxI software version 5.1

TRADEMARKS

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Introduction

The UniCel DxC Integrated Workstation* combines a UniCel DxC analyzer, a UniCel DxI analyzer, and a UniCel Closed Tube Aliquotter (UCTA) into a single integrated system.

*Integrated Workstations:
- DxC 660i: DxC 600+UCTA+DxI 60i
- DxC 680i: DxC 600+UCTA+DxI 800
- DxC 860i: DxC 800+UCTA+DxI 600
- DxC 880i: DxC 800+UCTA+DxI 800
UniCel Closed Tube Aliquotter (UCTA)

The UCTA functions as a sample processing manager. It serves as a single point of entry for the integrated workstation. The UCTA utilizes piercing probes that eliminate the need to uncap and recap sample containers. When a sample has DxI testing requirements, the UCTA will create an aliquot which is transferred to the DxI for processing. The UCTA then transfers the sample container to the DxC for further processing. A sample containing tests ordered for both the DxI and DxC will have testing occur simultaneously on both analyzers.

The UCTA is self-contained and houses all electronics, hydropneumatics and fluid-handling utilities.

<table>
<thead>
<tr>
<th>Component</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 UCTA Load Tray</td>
<td>Sample racks are placed here</td>
</tr>
</tbody>
</table>
| 2 UCTA RUN Button | Initiate processing:
  - Racks are delivered to the UCTA shuttle
  - Racks pass the bar code reader for sample programming information
  - The UCTA shuttle delivers racks to the UCTA sample carousel |
| 3 UCTA PRIORITY Button | Used to interrupt rack loading to place a priority rack on the UCTA load tray |
| 4 UCTA STOP Button | Used to stop processing on the UCTA for emergency situations, for routine maintenance and diagnostic/alignment procedures |
| 5 UCTA door (located below the UCTA STOP button) | Compartment housing 2 sliding trays for UCTA Wash Buffer and UCTA Auto-Gloss |
The following table identifies some components used during sample processing.

**Diagram of an overhead view of the inside of the UCTA and the back of the DxI**

<table>
<thead>
<tr>
<th>Component</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>① UCTA Bar Code Reader</td>
<td>Sample requirements identified</td>
</tr>
<tr>
<td>② UCTA Sample Carousel</td>
<td>Sample racks are delivered here for processing</td>
</tr>
</tbody>
</table>
| Left and Right UCTA Piercer Probe and Aliquot Probe assemblies | • Piercer probes pierce caps of closed sample containers  
  • Aliquot probes aspirate an aliquot of sample and dispense the aliquot into a sample vessel (SV) |
| ④ UCTA SV Shuttle                 | Holds SVs when sample is being dispensed and transfers the SVs to the UCTA Pick and Place |
| ⑤ UCTA SV Nest                    | • Holds empty SVs for delivery to UCTA SV Shuttle for sample addition  
  • Holds SVs containing sample for delivery to UCTA Transfer Shuttle. |
| ⑥ UCTA Pick and Place             | Transfers SVs between the UCTA SV Shuttle, UCTA SV Nest, and the UCTA Transfer Shuttle |
| ⑦ UCTA Transfer Shuttle           | Transports SVs between the DxI and the UCTA                             |
| ⑧ DxI Pick and Place              | Transports SVs between the UCTA Transfer Shuttle and the DxI sample storage |
UniCel DxC Analyzer

The DxC analyzer performs in vitro determination of a variety of general chemistries, therapeutic drugs, proteins, and drugs of abuse.

The DxC can be divided into two sides: the Modular Chemistry (MC) side and the Cartridge Chemistry (CC) side.

Picture shows DxC 800 with canopy open
Modular Chemistry (MC)

The modular chemistry system is used to provide rapid analysis for chemistries identified in the table below. The reactions occur in individual reaction cup modules or in an ion selective electrode (ISE) module.

<table>
<thead>
<tr>
<th>MC Components</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>① DxC Sample Carousel</td>
<td>Sample racks delivered here for sample aspiration from both the MC and CC sample probe</td>
</tr>
<tr>
<td>② MC Sample Probe</td>
<td>Aspirates and delivers sample to the MC modules</td>
</tr>
<tr>
<td>③ Reaction Cup Modules</td>
<td>Performs rapid analysis at each individual reaction cup module. Module configuration is as follows: DxC 600: GLUCm DxC 800: GLUCm, BUNm, PHOSm, CREm, ALBm, and TPm</td>
</tr>
<tr>
<td>④ Electrolyte Injection Cup (EIC)</td>
<td>Sample delivered here for electrolyte analysis</td>
</tr>
<tr>
<td>⑤ Ion Selective Electrode (ISE) Module (below cover)</td>
<td>• Electrolyte analysis performed here</td>
</tr>
<tr>
<td></td>
<td>• Contains a flow cell housing 5 measuring electrodes: NA, K, CL, CO₂, CALC and 2 reference electrodes: NA and CO₂</td>
</tr>
<tr>
<td></td>
<td>• Contains a Ratio Pump for reagent delivery to the flow cell</td>
</tr>
</tbody>
</table>
**MC Reagent Compartment**

1. Reaction cup (number based on instrument configuration) and ISE reagents. CO₂ Alkaline Buffer reagent located within the ISE module.

2. MC reagent bar code reader (also used for UCTA reagents)

3. DxC hydropneumatics compartment (behind door) contains DxC Wash Concentrate, DxC Auto-Gloss and No Foam reagent
Cartridge Chemistry (CC)

The Cartridge Chemistry System provides random access analysis using cartridge reagents. The analysis is performed in glass cuvettes located in the reaction carousel where absorbance readings are taken by a multi-wavelength photometer.

Covers removed from the reaction carousel and the wash tower probes.

<table>
<thead>
<tr>
<th>CC Components</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Reagent Probes (2)</td>
<td>Aspirates and delivers reagent(s) to a cuvette in the reaction carousel</td>
</tr>
<tr>
<td>2 Reagent Mixer</td>
<td>Mixes reagents delivered to the cuvette</td>
</tr>
<tr>
<td>3 CC Sample Probe</td>
<td>Aspirates and delivers sample to the cuvette containing reagent(s)</td>
</tr>
<tr>
<td>4 Sample Mixer</td>
<td>Mixes sample and reagent(s) in the cuvette</td>
</tr>
<tr>
<td>5 Reaction Carousel</td>
<td>Houses cuvettes used for sample analysis</td>
</tr>
<tr>
<td>6 Photometer (below cover)</td>
<td>Takes absorbance readings at multiple wavelengths of contents in the cuvette</td>
</tr>
<tr>
<td>7 Wash Tower Probes (4)</td>
<td>Washes, rinses, and dries cuvettes between usage</td>
</tr>
<tr>
<td><strong>CC Component</strong></td>
<td><strong>Function</strong></td>
</tr>
<tr>
<td>------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Reagent Carousel</td>
<td>Refrigerated compartment with a capacity to hold 59 reagent cartridges</td>
</tr>
</tbody>
</table>
UniCel DxI Analyzer

The DxI Analyzer is an automated, random access immunoassay system used for the in vitro determination of a wide variety of immunoassays. The system utilizes chemiluminescent technology.

### Component Function

<table>
<thead>
<tr>
<th>Component</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Presentation Unit (SPU)</td>
<td>Sample racks are loaded here for maintenance, calibration, and independent mode operation</td>
</tr>
<tr>
<td>Vessel Hopper</td>
<td>Supplies empty vessels to the UCTA and DxI</td>
</tr>
<tr>
<td>Substrate bottles (2) DxI 600 bottles identified by</td>
<td>Substrate used for reactions</td>
</tr>
<tr>
<td>Reagent Load Tray (below door)</td>
<td>Reagent packs are loaded here. Equilibration area for substrate</td>
</tr>
<tr>
<td>Substrate Bar Code Reader</td>
<td>Use to read bar code information on substrate bottles</td>
</tr>
<tr>
<td>Liquid Waste Drawer</td>
<td>Liquid waste containers located in this drawer</td>
</tr>
<tr>
<td>Solid Waste Door</td>
<td>Solid waste container storage</td>
</tr>
<tr>
<td>Wash Buffer Drawer</td>
<td>Wash buffer containers located in this drawer</td>
</tr>
<tr>
<td>Power Switch (behind door)</td>
<td>Use to power on and off the DxI analyzer</td>
</tr>
<tr>
<td>DxI Pick and Place*</td>
<td>Transfers SVs between the DxI sample storage and UCTA Transfer Shuttle</td>
</tr>
<tr>
<td>Sample Storage*</td>
<td>Refrigerated compartment that holds SVs</td>
</tr>
<tr>
<td>Reagent Pipettors (DxI 800 has 4 and DxI 600 has 2)*</td>
<td>Delivers sample and reagent to reaction vessels (RVs) and mixes the contents in the RVs</td>
</tr>
<tr>
<td>Reagent Storage*</td>
<td>Refrigerated compartment capable of holding 50 DxI reagent and diluent packs</td>
</tr>
<tr>
<td>Analytical Module*</td>
<td>Consists of an incubator, a wash/read carousel for washing reaction vessels, and a luminometer to read light emitted from the RV</td>
</tr>
</tbody>
</table>

*Components located under DxI main upper covers.
DxC Integrated Workstation Sample Processing Overview

Sample Processing*

The DxC Integrated Workstation Sample Processing diagram identifies some of the system components used during sample processing. Use the diagram as a reference.

*For complete details on sample analysis refer to the DxC Integrated Workstation IFU.

- A sample is placed in an appropriate sample rack and loaded on the UCTA load tray (1)
- The UCTA RUN button (2) is pressed to initiate sample processing.
- Racks are delivered to the UCTA shuttle
- The UCTA shuttle transfers racks to the bar code reader (3) for sample programming information
- The UCTA shuttle delivers racks to the UCTA sample carousel (4)

Continued on next page
If the sample needs to be tested at the DxI analyzer:
- A sample container is pierced by a piercer probe (5) if a cap is present
- Sample is aspirated by an aliquot probe (5) and delivered to an empty sample vessel (SV) on the UCTA SV shuttle (6)
- The SV shuttle moves to the UCTA pick and place (7)
- The UCTA pick and place transfers the SV from the SV shuttle to the UCTA SV nest (8)
- The UCTA pick and place transfers the SV from the SV nest to UCTA transfer shuttle (9)
- The UCTA transfer shuttle moves to the DxI pick and place (10)
- The DxI pick and place transfers the SV from the UCTA transfer shuttle to the DxI sample storage (11)
- Empty SV(s) from the DxI sample storage are transferred to the SV shuttle for the next sample aliquot(s)

DxI analysis begins
- The SV is used as the sample for immunoassay testing
- A reagent pipettor delivers reagent and sample to a reaction vessel (RV)
- The RV is incubated then washed to remove unbound material; substrate is added to the RV for the chemiluminescent reaction
- The luminometer measures the amount of light generated from the RV; the measure light is converted to assay concentration

The UCTA shuttle moves the sample rack to the DxC load area.

If the sample needs to be tested at the DxC analyzer:
- The sample rack is delivered to the DxC sample carousel.

DxC analysis begins
- If the sample requires MC testing:
  * Sample is delivered to the MC reaction cups modules for reaction cup analysis and to the EIC for electrolyte analysis
- If the sample required CC testing:
  * The CC reagent probes deliver reagent to a cuvette; the reagent is warmed and photometer takes reagent blank readings
  * Sample is delivered to the cuvette
  * The photometers takes reaction readings; the readings are converted to analyte concentration
  * The cuvette wash station washes, rinses, and dries the cuvette for resuse

When the sample is no longer needed for testing, the DxC shuttle moves the sample rack to the DxC off-load area.
Chapter 2
Software Overview

Introduction

The DxC Integrated Workstation operating and programming functions are initiated from the workstation console. The screen provides status information which allows the operator to determine the present state of the integrated workstation.

The DxI console is used for DxI specific functions such as calibration, maintenance, diagnostics, and independent mode operation.

Navigation

The DxC Integrated Workstation provides three software navigation methods* that you can use to select an item on a screen or in a window.

<table>
<thead>
<tr>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use the touch screen</td>
</tr>
<tr>
<td>Use the mouse and click on a selected item</td>
</tr>
<tr>
<td>Press a keyboard equivalent function or tab key to select an item</td>
</tr>
</tbody>
</table>

*Both the workstation console and the DxI console use the three software navigation methods.
### Workstation Console Common Screen Elements

<table>
<thead>
<tr>
<th>Status Indicators</th>
<th>Status Description</th>
</tr>
</thead>
</table>
| 1 **CTS**         | • Appears when the Closed Tube Sampling (CTS) feature is installed and enabled  
                     • ![CTS](image) Appears when the feature is not enabled |
| 2 Reagent Load Status | • Appears if there is a waiting period before a reagent can be loaded on the DxC |
| 3 Host Communication Bar | • Displays communication between the host and the DxC Integrated Workstation  
                              • ![BLUE](image) bar indicates that the host is sending information  
                              • ![GREEN](image) bar indicates that the host is receiving information  
                              • ![Host](image) Indicates the host and the workstation are not communicating |
| 4 Instrument Status | • Displays the operating status for the entire Integrated Workstation  
                         • The system components are listed: Dxl | UCTA | DxC (MC/CC) |
| 5 Printing Status  | • ![Printing](image) Indicates you must reboot the system to restart printing |
| 6 Dxl Console Status | • Reflects the status for the Dxl Event Log, Sample Manager Exceptions or Work Pending (QC rerun only)  
                         • Yellow and red color changes indicate Dxl investigation needed |
| 7 Menu Bar         | • Icons used to access the functional areas within the system |
### Menu Bar Icon Background Colors

<table>
<thead>
<tr>
<th>Color</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutral</td>
<td>No action is required</td>
</tr>
<tr>
<td>Yellow</td>
<td>Indicates a caution condition that requires investigation</td>
</tr>
<tr>
<td>Red</td>
<td>Indicates a warning condition that requires immediate attention</td>
</tr>
</tbody>
</table>

### Menu Bar Icons

<table>
<thead>
<tr>
<th>Icon</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="Image" alt="Main" /></td>
<td>View on board sample status information on the DxC, UCTA and DxI and perform Main Screen functions</td>
</tr>
<tr>
<td><img src="Image" alt="Samples" /></td>
<td>Perform sample programming functions for patients and quality control</td>
</tr>
<tr>
<td><img src="Image" alt="Results" /></td>
<td>Recall and print test results</td>
</tr>
<tr>
<td><img src="Image" alt="Rgts/Cal" /></td>
<td>View/print supply, reagent and calibration status and perform reagent and calibration functions for UCTA and DxC</td>
</tr>
<tr>
<td><img src="Image" alt="QC" /></td>
<td>Define and manage quality control</td>
</tr>
<tr>
<td><img src="Image" alt="Setup" /></td>
<td>Perform system setup functions</td>
</tr>
<tr>
<td><img src="Image" alt="Utils" /></td>
<td>Perform specific hardware functions on the DxC and UCTA (Examples: Maintenance, Prime, Alignments, Diagnostics)</td>
</tr>
<tr>
<td><img src="Image" alt="Status" /></td>
<td>View DxC and UCTA hardware status information such as temperature and voltages</td>
</tr>
<tr>
<td><img src="Image" alt="Instr Cmd" /></td>
<td>Initiate DxC and UCTA instrument commands (Examples: Home, Shutdown)</td>
</tr>
<tr>
<td><img src="Image" alt="Help" /></td>
<td>View the DxC Integrated Workstation Instructions for Use (IFU) Manual</td>
</tr>
</tbody>
</table>
Workstation Console Main Screen

The main screen displays the status information for all samples loaded onto the system. Status information is sorted by instrument and the information for each area is displayed on separate tabs.

<table>
<thead>
<tr>
<th>Screen Elements</th>
<th>Description</th>
</tr>
</thead>
</table>
| **1 Sample Status Tabs** | Select a tab to identify the location and status of samples:  
- **DxI** Samples in the DxI  
- **UCTA** Samples in the UCTA sample carousel  
- **DxC** Samples in the DxC sample carousel |
| **2 Sample Status Icons** | Identify the status of a sample. The icon is displayed in front of the sample ID. The sample status icons are specific to the tab selected. More information on the next page |
| **3 Rack/Sample Status Area** | Displays sample status for on-board samples. The format is different based on the tab selected |
| **4 Function Buttons** | Use to perform actions or display additional areas specific to the screen displayed |
| **5 Message Line** | Displays instructions for the next action required or error messages |
**Workstation Console Main Screen**

Sample Status Icons are available from each tab to view the status of onboard samples. The icon is displayed in front of the Sample ID.

<table>
<thead>
<tr>
<th>Sample Status Icons</th>
<th>Status Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>‿ Not Programmed</td>
<td>There is no programming for the sample ID</td>
</tr>
<tr>
<td>✗ Query Pending</td>
<td>System is waiting for sample programming to be downloaded from the host</td>
</tr>
<tr>
<td>⏳ In Progress</td>
<td>Sample testing is in progress</td>
</tr>
<tr>
<td>🍄 Aspirated</td>
<td>Sample aspiration is complete (DxC and DxI tabs only)</td>
</tr>
<tr>
<td>🟢 Incomplete</td>
<td>The system is unable to complete at least one test</td>
</tr>
<tr>
<td>🏷 Aliquoted</td>
<td>Sample has been aliquotted for testing (UCTA tab only)</td>
</tr>
<tr>
<td>✅ Complete</td>
<td>All tests have been completed</td>
</tr>
</tbody>
</table>
## DxI Console Main Menu

The DxI console is used for DxI calibration, maintenance, diagnostics/alignments and during independent mode operation.

### Screen Element | Description
--- | ---
1. **System Mode** | Indicates the status of the DxI analyzer. The modes consist of: Ready, Running, Paused or Not Ready
2. **Status Buttons** | System Status buttons can be viewed at any time. Select the button to view its related screen. See the next page for details
3. **Command Buttons** | Use to Stop, Pause or Resume operation of the DxI
4. **UCTA/DxC Status Button** | Displays the software version and system status for the DxC and UCTA
5. **Help Button** | The Help system includes detailed operating and reference information specific to the DxI instrument
6. **Function Buttons** | Use to access all functional areas of the DxI software. The function buttons are screen-specific
## DxI Main Menu System Status Buttons

<table>
<thead>
<tr>
<th>System Status Buttons</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exceptions</strong></td>
<td>The Exceptions view of the Sample Manager screen lists samples that have errors such as QNS. A color change of this icon at the DxI console will also appear at the workstation console.</td>
</tr>
<tr>
<td><strong>Work Pending</strong></td>
<td>The Work Pending will turn yellow if DxI QC is reordered at the DxI console using the Rerun Test function button. A color change of this icon at the DxI console will also appear at the workstation console.</td>
</tr>
<tr>
<td><strong>Supplies Required</strong></td>
<td>The Supplies Required screen displays information about needed supplies or calibrations, or if an instrument condition requires attention.</td>
</tr>
<tr>
<td><strong>Bulk Supplies</strong></td>
<td>The Bulk Supplies screen displays information about the available quantities of the bulk supplies and space available conditions for waste containers.</td>
</tr>
</tbody>
</table>
| **Quality Control**   | Used to designate a specific reagent pipettor for DxI QC testing.  
*Note:* All other DxI QC functions are disabled on the DxI console because QC is defined and managed at the workstation console. |
| **Event Log**         | The Event Log displays information about events generated by the system, including informational, warning and caution events. A color change of this icon at the DxI console will also appear at the workstation console. |

### System Status Button Background Colors

<table>
<thead>
<tr>
<th>Neutral</th>
<th>Normal conditions; no action is required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>Indicates a caution condition/event that requires investigation</td>
</tr>
<tr>
<td>Red</td>
<td>Indicates a warning condition/event that requires immediate attention</td>
</tr>
</tbody>
</table>
### DxI Main Menu Function Buttons

<table>
<thead>
<tr>
<th>Function</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample Manager</strong> &lt;br&gt; F1</td>
<td>Manages routine functions associated with samples. &lt;br&gt;Note: During routine DxC Integrated Workstation operations, this function button is used to program calibration requests and maintenance routines.</td>
</tr>
<tr>
<td><strong>Test Results</strong>  &lt;br&gt; F2</td>
<td>Recalls DxI assay results.</td>
</tr>
<tr>
<td><strong>Supplies</strong>  &lt;br&gt; F3</td>
<td>Used to view DxI supplies and unload DxI reagent packs.</td>
</tr>
<tr>
<td><strong>Quality Control</strong> &lt;br&gt; F4</td>
<td>Used to designate a specific reagent pipettor for DxI QC testing. &lt;br&gt;Note: All other DxI QC functions are not available on the DxI console because QC is defined and managed at the workstation console.</td>
</tr>
<tr>
<td><strong>Calibration</strong>  &lt;br&gt; F5</td>
<td>Used to define DxI calibrators, view and/or print DxI calibration reports.</td>
</tr>
<tr>
<td><strong>Maintenance Review</strong> &lt;br&gt; F6</td>
<td>Accesses a review of DxI system temperatures and review results for non-routine maintenance procedures.</td>
</tr>
<tr>
<td><strong>Diagnostics</strong>  &lt;br&gt; F7</td>
<td>Used to initialize the DxI analyzer, prime fluidics and perform diagnostic/alignment and troubleshooting procedures.</td>
</tr>
<tr>
<td><strong>Configure</strong>  &lt;br&gt; F8</td>
<td>Configure DxI setup features (not all features are available on a DxC Integrated Workstation).</td>
</tr>
</tbody>
</table>
Integrated Workstation Software Tree

- **Main**
  - **DxC**
    - F1 Results
    - F2 Unload
    - F6 Log
    - F9 Pre Run
    - F10 Post Run

- **Samples**
  - **F2 Demog**
    - F1 Sample
    - F2 Edit
    - F3 Urine
    - F10 Next

  - **F3 Options**
    - Sample Replicates
    - Serum Index
    - Off-line Dilution Factor
    - Reps
    - Manual ORDAC
      - OK
      - Cancel

  - **F4 Batch**
    - Clear
    - Smp ID Only
    - Rack(s)
    - No. of Samples in Batch
    - OK
    - Cancel

  - **F5 Control**
    - Select Control
    - Cancel

  - **F6 Rerun**
    - Sample IDs (From/To)
    - Rack(s)/Position(s)
    - Select
    - All
    - Batch
    - Cancel

  - **F7 Clear**
    - Sample IDs (From/To)
    - Rack(s)/Position(s)
    - Date/Time (From/To)
    - OK
    - Cancel

  - **F8 Racks**
    - F1 Clear
    - F9 Cancel
    - F10 Program

  - **F9 List**
    - Sample IDs (From/To)
    - Rack(s)/Position(s)
    - Date/Time (From/To)
    - Status
    - Print
    - Display
    - Cancel

  - **F10 Next**
    - Sample Required
    - In Progress
    - Complete
    - Incomplete
    - Rerun
    - Manual Assign
<table>
<thead>
<tr>
<th>Setup, continued</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5. Immediate Report</strong></td>
</tr>
<tr>
<td>STAT Host/Printer</td>
</tr>
<tr>
<td>ALL Host/Printer</td>
</tr>
<tr>
<td>Immediate Report of DxC</td>
</tr>
<tr>
<td>Immediate Report of Serum Index</td>
</tr>
<tr>
<td>Immediate Report of Dx By Test</td>
</tr>
<tr>
<td>Immediate Report of Critical Rerun</td>
</tr>
<tr>
<td>OK</td>
</tr>
<tr>
<td>Cancel</td>
</tr>
<tr>
<td>F1 Define</td>
</tr>
<tr>
<td>F2 Delete</td>
</tr>
<tr>
<td>F3 Default</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>6. Panels</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>F1 Restore</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>7. Replicates</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>F1 Restore</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>8. Report Setup</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Header</td>
</tr>
<tr>
<td>Report Format (Patient)</td>
</tr>
<tr>
<td>Continuous Lab Report</td>
</tr>
<tr>
<td>Chart Report Format A</td>
</tr>
<tr>
<td>Lab Report</td>
</tr>
<tr>
<td>Lab Report with raw data</td>
</tr>
<tr>
<td>Control</td>
</tr>
<tr>
<td>Control Chart Report</td>
</tr>
<tr>
<td>Control Chart Report with raw data</td>
</tr>
<tr>
<td>Disable Reports</td>
</tr>
<tr>
<td>Print Patient and Control Reports</td>
</tr>
<tr>
<td>Print Only Patient Report</td>
</tr>
<tr>
<td>Print Only Control Report</td>
</tr>
<tr>
<td>Print Options</td>
</tr>
<tr>
<td>Inter-Laboratory</td>
</tr>
<tr>
<td>F1 Restore</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
<tr>
<td>ID-Number</td>
</tr>
<tr>
<td>Attention Person</td>
</tr>
<tr>
<td>F3 Cal</td>
</tr>
<tr>
<td>Print Calibration Reports</td>
</tr>
<tr>
<td>Archive Calibration Warnings</td>
</tr>
<tr>
<td>F1 Restore</td>
</tr>
<tr>
<td>F8 Prev</td>
</tr>
<tr>
<td>F9 Next</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
<tr>
<td>Cancel</td>
</tr>
<tr>
<td>Suppress Results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>9. Reportable Ranges</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Define/Edit</td>
</tr>
<tr>
<td>Cancel</td>
</tr>
<tr>
<td>F1 Delete</td>
</tr>
<tr>
<td>F2 Clear All</td>
</tr>
<tr>
<td>F3 Default</td>
</tr>
<tr>
<td>F8 Previous</td>
</tr>
<tr>
<td>F9 Next</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
<tr>
<td>Sample Type</td>
</tr>
<tr>
<td>Sex M/F</td>
</tr>
<tr>
<td>Summary by Sample Type</td>
</tr>
<tr>
<td>Summary by Serum of Type</td>
</tr>
<tr>
<td>Summary by CSF</td>
</tr>
<tr>
<td>Summary by Plasma</td>
</tr>
<tr>
<td>Summary by Random Urine</td>
</tr>
<tr>
<td>Summary by Timed Urine</td>
</tr>
<tr>
<td>Summary by Blood</td>
</tr>
<tr>
<td>Summary by Amniotic</td>
</tr>
<tr>
<td>Summary by Urethral</td>
</tr>
<tr>
<td>Summary by Saliva</td>
</tr>
<tr>
<td>Summary by Cervical</td>
</tr>
<tr>
<td>Summary by Synovial</td>
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<tr>
<td>Summary by Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>10. Reference/Critical Ranges</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Define/Edit</td>
</tr>
<tr>
<td>Clear Ranges</td>
</tr>
<tr>
<td>F1 Delete</td>
</tr>
<tr>
<td>F2 Clear All</td>
</tr>
<tr>
<td>F3 Default</td>
</tr>
<tr>
<td>F8 Previous</td>
</tr>
<tr>
<td>F9 Next</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
<tr>
<td>Sample Type</td>
</tr>
<tr>
<td>Sex M/F</td>
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</tbody>
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<table>
<thead>
<tr>
<th><strong>11. Sample Comments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>F10 Done</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>12. Special Calculations</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>F1 View</td>
</tr>
<tr>
<td>F2 Define</td>
</tr>
<tr>
<td>F3 Delete</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
<tr>
<td>Enable</td>
</tr>
<tr>
<td>Calibration No.</td>
</tr>
<tr>
<td>F1 License</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>13. Version Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>F1 License</td>
</tr>
<tr>
<td>F10 Done</td>
</tr>
<tr>
<td>OK</td>
</tr>
<tr>
<td>14. Units/Precision</td>
</tr>
<tr>
<td>---------------------</td>
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<td></td>
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<tr>
<td>15. User-Defined Chemistries</td>
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<td>16. Barcode</td>
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<td>17. Obstruction Detection</td>
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<td>18. Disable Service Monitor</td>
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<td>19. Language/Keyboard</td>
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<td>20. Host Communication</td>
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<tr>
<td>21. Language/Keyboard</td>
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<td>22. Printer Setup</td>
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<td></td>
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<tr>
<td>23. Service Setup</td>
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<tr>
<td></td>
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<tr>
<td>24. System Configuration</td>
</tr>
<tr>
<td></td>
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<tr>
<td>25. Version Upgrade</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Setup, continued</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Utils</th>
<th>1. Prime</th>
<th>F1 Prime All CC Subsystems All Hydropneumatic Subsystems All MC Subsystems Prime DxC All UCTA Wash All UCTA Auto-Gloss CTS Auto-Gloss CTS Blade Wash Number of Primes to Repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Reagent Delivery Subsystem Sample Delivery Subsystem Cuvette Wash Number of Primes to Repeat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fill Canisters and reservoirs CC Drain waste sump CC Drain waste B sump Drain gravity drain sump</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cup Selection: ALBm (DxC 800 only) CREm (DxC 800 only) GLUCm PHOSm (DxC 800 only) TPm (DxC 800 only) BUNm (DxC 800 only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prime Cup(s) with: Reagent DI Water</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sample Delivery Subsystem ISE All Electrolyte Buffer Electrolyte Reference EIC/SCC Wash ISE CO2 Alkaline Buffer Reference and Acid Number of Primes to Repeat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>F4 MC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prime Cup(s) with: Reagent DI Water</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sample Delivery Subsystem ISE All Electrolyte Buffer Electrolyte Reference EIC/SCC Wash ISE CO2 Alkaline Buffer Reference and Acid Number of Primes to Repeat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>F5 UCTA Start Prime Stop Prime F10 Exit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Probe Wash Auto-Gloss</td>
</tr>
</tbody>
</table>
2. Maintenance

1. CTS Blade Replacement
2. Cartridge Chemistry Probe Cleaning
3. ISE Service
4. Cup Maintenance
5. Hydropneumatic Maintenance
6. Wash All Cuvettes
7. Syringe Maintenance
8. CUPs Lamp/Sensor Calibration
9. CC Reagent Wash All Cuvettes
10. Clean Flow Cell, Cups & CC Probes/Mixers

3. Event Log

Display
Copy
Time
Clear
Print
Done
1. Chemistry Errors
2. Motion Errors
3. Status Monitor Errors
4. Other Instrument Errors
5. Instrument Events
6. LIS Comm. Errors
7. Other Console Errors
8. Input Device Events
9. Other Console Events
10. Sample Processing Events
11. Deleted Results
12. Dxl Communications
13. UCTA Events

4. Diagnostics

Functional Area
Sub-functional Area
Test No.
F10 Exit

Electrode Maintenance Drain
Sample Dilution Cup (SDC) Maintenance
Prime20
Prime5
Drain
Rinse
Cancel
Albumin (DxC 800 only)
BUNm (DxC 800 only)
Creatinine (DxC 800 only)
Glucose
Phosphorus (DxC 800 only)
Total Protein (DxC 800 only)
Syringe or Syringe Plunger Replacement
Albumin (DxC 800 only)
BUNm (DxC 800 only)
Creatinine (DxC 800 only)
Glucose
Phosphorus (DxC 800 only)
Total Protein (DxC 800 only)
CC Probes/Mixers
CC Cuvettes
Start
Close
Available Racks
Rack Number
ISE/MC Rack
CC Rack
Scheduled Maintenance Log
Initial/Date
Print
Approve
Done
Sample System
Reagent System
Resection System
Hydropneumatic System
ISE Module System
Modular Cup Chemistry Module
Valve and Fluidics
Based on Functional Area selected
Based on Sub-Functional Area selected
Chapter 3
Daily Start Up

Introduction

These procedures ensure that you complete all steps required before a patient run.

Supply Capacities

The following tables identify the supply capacities for each instrument component. All supplies required can be viewed using the appropriate supply tabs available within the Rgts/Cal icon at the workstation console.
## DxI Supplies

<table>
<thead>
<tr>
<th>DxI Supply</th>
<th>Capacity</th>
<th>Yellow Caution</th>
<th>Red Warning</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash Buffer</td>
<td>2 x 10 L</td>
<td>1 Container Empty</td>
<td>Both Containers Empty</td>
<td>• Red Warning: Completes testing in progress, but no new tests scheduled</td>
</tr>
<tr>
<td>Liquid Waste</td>
<td>DxI 800: 2 x 9.5 L</td>
<td>1 Container Full</td>
<td>Both Containers Full</td>
<td>• Red Warning: Completes testing in progress, but no new tests scheduled • Not used on systems plumbed directly to a drain</td>
</tr>
<tr>
<td></td>
<td>DxI 600: 2 x 5.0 L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reaction Vessels</td>
<td>1700-1800</td>
<td>&lt;1000</td>
<td>&lt;100</td>
<td>• Red Warning: When the vessel hopper is empty, it completes testing in progress, but no new tests scheduled</td>
</tr>
<tr>
<td>Solid Waste</td>
<td>DxI 800: 20 pounds (9.1 kg)</td>
<td>10% or less volume available in container for collecting waste</td>
<td>Container is Full</td>
<td>• Red Warning: When the container is full, it completes testing in progress, but no new tests scheduled</td>
</tr>
<tr>
<td></td>
<td>DxI 600: 10 pounds (4.6 kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substrate</td>
<td>2 x 130 mL (1200 tests)</td>
<td></td>
<td></td>
<td>• Red Warning: When both on-board bottles are empty or expired, the system completes any in progress tests, but no new tests scheduled</td>
</tr>
<tr>
<td>Reagent Packs</td>
<td>50 positions</td>
<td>&lt;10 tests left</td>
<td>Expired pack lot</td>
<td>• Supplies Required button turns yellow to alert operator when reagent is empty, expired or not calibrated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 days or less to lot expiration</td>
<td>Expired open stability</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 days or less to calibration expiration</td>
<td>Expired or not calibrated</td>
<td></td>
</tr>
</tbody>
</table>
## UCTA Supplies

<table>
<thead>
<tr>
<th>UCTA Supply</th>
<th>Capacity</th>
<th>Yellow Caution</th>
<th>Red Warning</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash Buffer</td>
<td>2 x 10 L</td>
<td>1 Container Empty</td>
<td>Both Containers Empty</td>
<td>• Red Warning: No new tests scheduled</td>
</tr>
<tr>
<td>Auto-Gloss</td>
<td>500 mL</td>
<td>• Pop-up messages at 10%, 5% and 0% volume remaining</td>
<td>• 0 tests available</td>
<td>• UCTA will off-load racks with 0% volume or reagent not loaded</td>
</tr>
</tbody>
</table>

## DxC Reagents

<table>
<thead>
<tr>
<th>DxC Reagent</th>
<th>Capacity</th>
<th>Yellow Caution</th>
<th>Red Warning</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MC Reagent*</td>
<td>500 mL or 2000 mL containers</td>
<td>• Pop-up messages at 10%, 5% and 0% volume remaining</td>
<td>• 0 tests available</td>
<td>• Prepare reagent according to Reagent Preparation Quick Reference or Chemistry Information Sheets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Days exceeded</td>
<td>• Reagent expired</td>
<td></td>
</tr>
<tr>
<td>CC Reagent</td>
<td>59 reagent positions</td>
<td>• Pop-up messages at 5 and 0 tests remaining in cartridge</td>
<td>• 0 tests available</td>
<td>• Prepare reagent according to reagent cartridge label, Reagent Preparation Quick Reference, or Chemistry Information Sheets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Days exceeded</td>
<td>• Reagent expired</td>
<td></td>
</tr>
</tbody>
</table>

*Wash Concentrate II will not display yellow or red messages.*
Daily Start Up
The following procedures are required for a daily start up of the DxC Integrated Workstation. The order listed below is the most efficient way to complete the procedures.

1. Determine integrated workstation supply and calibration status
2. Perform DxI daily maintenance
3. Replenish DxI supplies and reagents
4. Replenish UCTA supplies
5. Replenish DxC reagents
6. Calibrate DxC chemistries (as needed)
7. Calibrate DxI assays (as needed)
8. Process quality control
9. Clear manually assigned racks

Note: Verify the current daily start up procedures by referencing the latest version of the DxC Integrated Workstation Instructions for Use (IFU) Manual and the Important Notes for the IFU.

Flowchart Information
- Perform the tasks in the order listed for efficiency
- Some tasks may be performed on one component of the system while another component is performing a different task. Multi-tasking reduces start up time
- Some tasks may be performed at alternate times
  (Example: DxI assays may be calibrated during off-peak hours)
- All tasks may not be required each day
  (Example: Not all assays need to be calibrated daily)
- Colors are used to categorize groups of tasks
DxC Integrated Workstation Daily Start Up

Print/View Integrated Workstation supply, reagent, and calibration status

Perform the following DxI Daily Maintenance procedures (Utility Assay enabled):
~ Check System Backup
~ Shake Solid Waste Container
~ Run DxI Clean Routine
~ Initial and Date Electronic Maintenance Log

DxI supplies* required?

Yes → Load DxI supplies

No →

UCTA supplies required?

Yes → Load UCTA supplies

No →

DxC reagents required?

Yes → Load DxC reagents

No →

DxC calibration required?

Yes → Calibrate DxC chemistries

No →

DxI calibration required?

Yes → Calibrate DxI assays

No →

Process Quality Control

Clear racks

*Note: DxI supplies can be loaded while the Clean Routine is processing, except when changing the Solid Waste.
View / Print Supply, Reagent, and Calibration Status

Select Rgts/Cal from the workstation console

View all tabs and pages or select Print F10
Check DxI Backup

Select **Main Menu** or the **Menu** tab from the DxI console

Select **Configure F8**

Select **PC Admin F7**

Verify a successful backup by viewing the status in the Last Backup field*

Backup to flash drive or tape?

- **Flash Drive**
- **Tape**

Select **Eject Tape F3**

A message will display when the tape is ejected. Remove the tape from the DxI PC tape drive

Insert an alternate tape in the DxI PC tape drive

Document completed maintenance in Electronic Maintenance Log

*Note: If the backup is not successful, perform an immediate backup or schedule a backup. The instructions for the procedures can be found in the DxI Help System.
Shake the Dxl Solid Waste Container

1. Verify the Dxl is not running the Daily or Special Clean routine or initializing*
2. Open the solid waste door at the Dxl
3. Grasp the solid waste container and gently shake the container to distribute the contents evenly
4. Close the solid waste door
5. Document completed maintenance in Electronic Maintenance Log

*Caution: Opening the solid waste door during any of these procedures will place the Dxl in Not Ready
Process Daily Clean Routine

Select **Main Menu** or the **Menu** tab from the Dxl console

Select **Sample Manager F1**

Select **New Request F3**

Select **Maintenance F3**

At the **Request Maintenance** Screen

Select **Daily Clean System**

Select **OK F1**

Enter the rack ID and press **Enter**

Use the load list displayed on the screen to place the appropriate cleaning solutions in the correct position on the rack

Load the rack on the Dxl Sample Presentation Unit (SPU)

Document completed maintenance in Electronic Maintenance Log

*If you run the B12 assay, perform the Special Clean in place of the Daily Clean. See the Dxl Help System for information about running the Special Clean*

**CAUTION**
Citranox and Conrad 70 cleaning solutions may cause eye or skin irritation. See the MSDS for details
Add Reaction Vessels (RVs)

1. Open the vessel hopper door
2. Open the bag of RVs and pour the contents into the vessel hopper
3. Close the vessel hopper door
Change a Full Liquid Waste Container

1. Use supply status to determine which bulk liquid waste container(s) needs to be changed
2. Pull out the liquid waste drawer
3. Press the disconnect button on the full container to release the tubing
4. Remove the full container and replace it with an empty container
5. Connect the tubing to the empty container and close the drawer
6. Decontaminate* the contents of the full container and dispose of the liquid waste
7. Rinse the container thoroughly and store it for future use

*Decontaminate liquid waste based on laboratory protocol
Change an Empty DxI Wash Buffer Container

1. Use supply status to determine which container(s) of wash buffer needs to be replaced.
2. Pull out the wash buffer supply drawer.
3. Remove the perforated cardboard panels of the new container and gently invert the container 3-4 times.
4. Extend the neck of the new container and remove the cap and inner seal.
5. Press the disconnect button on the empty container to release the tubing.
6. Remove the empty container from the drawer and replace it with the new container.
7. Remove the cap/draw tube assembly from the empty container and insert it into the new container.
8. Connect the tubing to the new container and close the drawer.

*Lot number tracking requirement defined by laboratory policy

**Lot number tracking required?**

- Yes: Select Rgts/Cal from the workstation console.
- No: Select the Supplies tab.

Type the lot number into the DxI Wash Buffer field (Rear or Front) located in the DxI Supplies Status section of the screen.

Procedure complete.
Change an Empty or Expired Substrate

1. Use supply status to determine which bottle(s) of substrate to replace
2. Open the substrate load door and release the load tray
3. Remove the empty or expired bottle and discard
4. Remove a new bottle from the substrate equilibration area
5. Remove the cap from the new bottle and place the bottle in the load tray with the bar code facing out
6. Push in the load tray until it locks in place and the system closes the door
7. Scan the bar code label
8. Place an unequilibrated bottle in the substrate equilibration area
Change a Full Solid Waste Container

1. Verify the DxI is not running the Daily or Special Clean routine or initializing*
2. Pull down on the solid waste door handle
3. Slide the full container out of the storage area and seal the waste bag
4. Remove the full waste bag and insert a new bag into the container
5. Slide the empty container and bag into the storage area
6. Press the green reset button and close the door

*Caution: Opening the solid waste door during any of these procedures will place the DxI in Not Ready
Load DxI Reagent Pack

Check the status of the reagent tray in-use light

Is the light on?

Yes: Wait until the green light turns off

No: Gently mix the packs and open the reagent load door

Place pack(s) in the tray positions

Close the reagent load door

More reagent pack(s) to load?

Yes: Repeat the process

No: Procedure complete
Unload a DxI Reagent Pack

Select **Main Menu** or **Menu** tab from the DxI console

Select **Supplies F3**

Select **Reagent Supplies F2**

Select **Unload Reagent Packs F2**

Select pack(s) to unload*

Wait for the reagent tray in-use light to turn off

Open the reagent door and remove the pack(s)

Close the reagent load door

*To unload all packs on board, select **Unload All Reagent Packs F3**

More packs to unload?

Select Exit F1
**Change an Empty UCTA Wash Buffer Container**

1. Use supply status to determine which container(s) of wash buffer needs to be replaced.
2. Open the UCTA door and pull out the lower sliding tray to gain access to the wash buffer container.
3. Lift the empty container from the lower sliding tray and place it on the floor adjacent to the tray.
4. Remove the perforated cardboard panels at the top and sides of the new container. Gently mix the new container of wash buffer.
5. Place the new wash buffer container onto the lower sliding tray.
6. Grasp the cap on the new container and pull upward until the plastic neck is completely extended.
7. Remove the neck guard from the empty container and slip it on the plastic neck of the new container. Remove the cap and inner seal from the new container.
8. Unscrew the cap/draw tube assembly on the empty container and carefully remove it from the container. Lower the the cap/draw tube assembly into new container and tighten the cap.
9. Push in the sliding lower tray and close the UCTA door.

**Lot number tracking required?**

- **Yes:**
  - Select Rgts/Cal from the workstation console.
  - Select the Supplies tab.
  - Type the lot number into the UCTA Wash Buffer field (Rear or Front) located on the UCTA Supplies Status section of the screen.

- **No:**
  - Procedure complete.

*Lot number tracking requirement defined by laboratory policy.*
Change the UCTA Auto-Gloss

1. Open the UCTA door
2. Pull out the upper sliding tray where the Auto-Gloss bottle is located behind the syringes
3. Unfasten the cap and inlet tubing and remove the old Auto-Gloss bottle
4. Place the cap and inlet tubing in the new bottle and place the new Auto-Gloss bottle on the system
5. Select **Rghts/Cal** from the workstation console
6. Select the **Supplies** tab
7. Select **Load** located in the UCTA Supplies Status column
8. Use the DxC hand held bar code reader to scan the bar code on the Auto-Gloss bottle. Verify the new reagent information is displayed
9. Select **Done F1**
10. Push the upper sliding tray in
11. Close the UCTA door
Load MC Reagents

1. Prepare reagent(s) if required

2. Select `Rgts/Cal` from the workstation console

3. Select the `DxC` tab

4. Select `MC Rgts`

5. Select `Load F1`

6. Open the MC reagent compartment door of the DxC analyzer

7. Disconnect the straw(s) from the fitting(s) and remove the reagent from the tray. Place the cap/draw tube assembly from the old bottle onto the new bottle. Place the new reagent on the tray and reconnect fitting(s) to the straw(s)

   Notes: Take care not to contaminate the draw tube. Discard the old bottle according to laboratory procedures

8. Use the bar code reader to scan the reagent bar code label on the new reagent bottle. Verify the new reagent information is displayed

9. Place the new bottle into the reagent storage area

10. More MC reagents to load? (Yes/No)

11. Select `Done F10`

12. Close the MC reagent compartment door
Load CC Reagents

1. Prepare reagent(s) if required
2. Remove caps, remove any liquid adhering to the chimneys of the cartridge and remove any bubbles on the surface of the reagent
3. Select **Rgts/Cat** from the workstation console
4. Select the **DxC** tab
5. Page down (pages 3-8) to locate the position(s) on the CC carousel where reagents will be placed
6. Select all **positions** to load reagent cartridges
7. **Select Load F1**
   - When prompted by the software, open the reagent carousel door
   - Place cartridge in the load position in front of the blinking bar code reader beam. Verify the reagent information is displayed on the workstation console. Move the cartridge onto the reagent carousel
8. Close the reagent carousel door
9. **Additional reagents selected?**
   - Yes
   - No
10. Procedure complete
Unload CC Reagents

Select **Rgts/Cal** from the workstation console

Select the **DxC** tab

Page down (pages 3-8) to locate the position(s) of the reagent(s) to be unloaded from the CC carousel

Select position(s) to unload reagent cartridges

Select **Load F1**

Open the reagent carousel door when prompted

Grasp the cartridge in the load position (located at the blinking bar code reader) and move it in front of the bar code reader beam. Verify the reagent information is removed from the screen. Remove the cartridge

Close the reagent carousel door

Additional reagents selected?

- Yes
- No

Procedure complete
Calibrate DxC Chemistries

Select **Rgts/Cal** from the workstation console

Select the **DxC** tab

Select each chemistry for calibration. Page down to view additional chemistries

Select **Cal F4**

Select **List F5**

Review the calibrator load list. Verify the calibrator lot number in use matches the load list. Note: For some calibrators, the lot number is N/A

Locate the racks to be used for calibration. Pour the calibrator(s) into sample cups and place the sample cups in either the assigned bar code labeled tube(s) or the assigned calibrator rack number and position

Place the rack(s) in the UCTA load tray

Press the **RUN** button on the UCTA.

When Calibration is complete view calibration status on Rghts/Cal screen

Calibration successful?

Consult references for troubleshooting assistance

Procedure complete
Calibrate DxI Assays

1. Select Main Menu or the Menu tab from the DxI console.
2. Select Sample Manager F1.
4. Select Calibration F2.
5. Select a calibrator set* from the Request Calibration screen.
7. Type the rack number(s) in the Enter ID field and select Enter after each rack.
8. Use the load list displayed on the screen to place the appropriate calibrators in the correct positions on the rack.
9. Load the rack(s) on the DxI Sample Presentation Unit (SPU).
10. When Calibration is complete, view calibration status on Rgts/Cal screen or on printed Calibration report.

- Calibration successful?
  - Yes: Procedure complete.
  - No: Consult references for troubleshooting assistance.
Process Quality Control using Auto Generation of Control

1. Locate the rack containing the bar code labeled tube(s) for the control sample(s)*
2. Pour the control material into a sample cup
3. Nest the sample cup in the appropriate bar code labeled tube(s)
4. Load the rack(s) on the UCTA load tray
5. Press the **RUN** button on the UCTA
6. When Quality Control is complete, review for acceptability**

**Quality Control acceptability defined by laboratory policy**

*To ensure all tests for your QC are processed following a manual run, reset auto generation of control by clearing the control IDs.

Quality Control acceptable?  

No: Consult references for troubleshooting assistance  
Yes: Procedure complete
Manually Program and Process Quality Control

Select **Samples** from the workstation console

Select **Clear F7**

Enter the QC ID to be cleared in the Sample ID field*

Select **OK**

Select **OK** to confirm

Type the Control ID in the Sample ID field

Enter the rack/position number in the rack/position fields if no QC bar code is available

Select the chemistries to be run

Select **Save F10**

Place the appropriate QC material into a cup and place the cup in the assigned rack and position or bar code labeled tube

Load the rack(s) on the UCTA load tray. Press the **RUN** button on the UCTA

When Quality Control is complete review for acceptability**

Quality Control acceptable?

Consult references for troubleshooting assistance

Procedure complete

*Multiple QC ID’s may be cleared by typing in each control ID separated by a comma.

**Quality Control acceptability defined by laboratory policy
Clear Racks

Select Samples from the workstation console

Select Clear F7

Type the range of rack numbers to be cleared in the Rack(s) field*

Note: Enter 1-999 to clear all racks.

Select Enter

Select OK F1

Select OK F1 to confirm

*Calibrator rack assignments and racks in progress are not cleared with this step.
Chapter 4
Sample Processing

Validated Sample Containers for Cap Piercing

The following containers have been validated for cap piercing on the UCTA and the CTS* (Closed Tube Sampling) on the DxC.

- Becton Dickinson VACUTAINER with HEMOGARD
  - 13 x 75 mm
  - 13 x 100 mm
  - 16 x 100 mm

- Greiner VACUETTE
  - 13 x 75 mm
  - 13 x 100 mm

*This information applies only to systems configured with a 1-Blade Thick CTS

Note: 1-Blade Narrow CTS on the DxC is used for 92 x 15 mm or 75 x 15 mm Sarstedt S-Monovette. These tubes are not commonly used in North America.

Minimum Sample Volume

All sample containers, sample cups and insert cups, must contain a minimum sample volume to run tests. The UCTA Primary Tube Sample Template identifies the volume of sample required to avoid sample and aliquot probe errors (QNS, probe motion errors, probes aspirating gel or blood clot). For primary tubes use the template to verify that the container has the required volume of sample for the tests ordered. For other sample containers (low volume) use the dead volume for each container to guide you.

Sample Racks

- Racks are available in multiple sizes and colors
- Racks are configured in the system software
- Racks are identified by the rack bar code
- Rack labels are available and can be attached to the racks to help the operator determine the appropriate rack in which to place a sample container

The 4 categories of sample racks are: Shared, DxC/UCTA, DxC Only and DxI Only
Shared Racks

Shared racks accommodate one container type per rack. Shared racks may be processed through the UCTA, placed directly on the DxC load area, or on the DxI SPU (with caps removed). Shared racks are the most commonly used racks.

<table>
<thead>
<tr>
<th>Shared Rack Labels</th>
<th>Use for:</th>
</tr>
</thead>
</table>
| **Shared 13 x 75 mm Tube** | Primary tube, 13 x 75 mm  
Secondary tube 12 or 13 x 75 mm |
| **Shared 13 x 100 mm Tube** | Primary tube 13 x 100 mm |
| **Shared 16 x 100 mm Tube** | Primary tube 16 x 100 mm |
| **Shared 92 x 15 (7.5 mL) Sarstedt S-Monovette Tube** | Primary tube 92 x 15 mm |
| **Shared 0.5 mL Sample Cup** | 0.5 mL Sample Cup (PN 651412)  
Dead volume* = 160 µL |
| **Shared 2.0 mL Sample Cup** | 2.0 mL Sample Cup (PN 652730 or 81902)  
Dead volume* = 420 µL |
| **Shared 1.0 mL INSERT Cup**  
13 x 75 mm Tube | 1.0 mL INSERT Cup (PN 81915) in a 13 x 75 mm tube  
Dead volume* = 310 µL |
| **Shared 1.0 mL INSERT Cup**  
13 x 100 mm Tube | 1.0 mL INSERT Cup (PN 81915) in a 13 x 100 mm tube  
Dead volume* = 310 µL |
| **Shared 2.0 mL INSERT Cup**  
16 x 100 mm Tube | 2.0 mL INSERT Cup (PN 81917) in 16 x 100 mm tube  
Dead volume* = 210 µL |

*Dead volumes identified for Shared racks include DxI and DxC dead volumes.
DxC/UCTA Racks

Racks defined as DxC/UCTA can be processed through the UCTA or placed directly on the DxC during independent mode operations. These racks cannot be loaded directly on the DxI SPU.

<table>
<thead>
<tr>
<th>DxC/UCTA Rack Labels</th>
<th>Use for:</th>
</tr>
</thead>
</table>
| **DxC/UCTA** 0.5 or 2.0 mL Sample Cup **5 mL Transfer Tube** | 0.5 mL Sample Cup in 5 mL Transfer Tube (PN 979272)  
Dead volume* = 160 µL  
2.0 mL Sample Cup in 5 mL Transfer Tube (PN 979272)  
Dead volume* = 210 µL |
| **DxC/UCTA** Pediatric INSERT Cup **13 x 75 Tube** | 1.0 mL Pediatric Insert Cup (PN 81916) in a  
12 or 13 x 75 mm tube  
Dead volume* = 160 µL |
| **DxC/UCTA** Pediatric INSERT Cup **13 x 100 Tube** | 1.0 mL Pediatric Insert Cup (PN 81916) in a  
13 x 100 mm tube  
Dead volume* = 160 µL |

*Dead volumes identified for DxC/UCTA racks include DxI and DxC dead volumes.

DxC Only Racks

Racks defined as DxC Only are validated to be used only when DxC tests are ordered. These racks are loaded through the UCTA or placed directly on the DxC during independent mode operations. The UCTA will not sample from the container for DxI testing since only DxC tests are ordered.

<table>
<thead>
<tr>
<th>DxC Rack Labels</th>
<th>Use for:</th>
</tr>
</thead>
</table>
| **DxC** SYNCHRON Microtube | SYNCHRON Microtube (PN 448774)  
Dead volume = 60 µL |
| **DxC** 0.5 mL Cup in Red Metal Insert | 0.5 mL Sample Cup in Red Metal Insert (PN 476406)  
Dead volume = 20 µL |
| **DxC** BD Microtainer Adapter | BD Microtainer in pediatric tube adapter (Adapter PN 472987)  
Dead volume = Not determined* |

*Refer to the UniCel DxC Synchron Clinical Systems Primary Tube Sample Template (PN 967178) for guidance on sample volume.
DxI Only Racks

Racks defined as DxI Only are loaded on the DxI SPU.

<table>
<thead>
<tr>
<th>DxI Rack Label</th>
<th>Sample Rack Type</th>
<th>Container Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Volume</td>
<td>Low Volume Sample Rack (PN A56423)</td>
<td>Low Volume Sample Vessel (DxI RV – PN 386167)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maximum allowable volume= 500 µL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dead volume = 60 µL</td>
</tr>
</tbody>
</table>

Additional Containers

Additional validated sample containers can be defined for use on DxC/UCTA only or DxI only. A complete list of validated containers can be found in the DxC Integrated Workstation Instructions for Use Manual.

Tips on Sample Preparation

- Remove visible blood from the top of capped tubes with a cotton tipped applicator stick moistened with DI water
- Verify there are no bubbles in the samples
- Verify that the bar code label is properly placed on the tube and is aligned so that it is visible through the slot in the rack
- Verify tubes are seated correctly in the appropriate rack
- Use only validated sample containers in racks specified for their use
- Use the UCTA Primary Tube Sample Template (PN A50304) to verify samples meet minimum and maximum volume requirements
- Do not overfill insert cups

Sample Processing

Samples may be processed using various programming methods on the DxC Integrated Workstation. Samples may be programmed at the LIS/HOST, at the Beckman Coulter Data Manager, or at the workstation console. Samples may be processed with or without bar codes. Use the flowcharts on the following pages to process samples based on sample volume, programming and bar code availability.

Note: Additional programming features are available such as batch mode, rerun, off-line dilution, serum index, manual ORDAC, etc. Detailed instructions for these options may be found in the DxC Integrated Workstation IFU or the UniCel DxC Synchron Clinical Systems Reference Manual.

Independent Mode Operations

The DxC Integrated Workstation is designed to allow the DxI analyzer or the DxC analyzer to operate independently. For more information on independent mode operations refer to the DxC Integrated Workstation IFU.
Sample Processing

Remove visible blood from the top of capped tubes using a cotton tipped applicator stick moistened with DI water

*Adequate sample volume determined by UCTA Primary Tube Sample Template

*Adequate Sample Volume?

Yes

No

Use “Low Volume Sample Processing” flowchart

Is sample programmed at the LIS?

Yes

No

Is there a readable bar code?

Yes

No

1 Select Samples from the workstation monitor
2 Enter Rack/Pos if bar code is not available
3 Enter Sample ID
4 Select Chemistries
5 If needed, select STAT check box, Sample Type, Sample Comment and/or Demog F2
6 Select Next F10

Place bar coded container in appropriate rack. Ensure that bar code label is visible through the rack slot. Verify tube is seated properly

Place sample in the rack and position identified above

Open UCTA cover and place rack in the load tray with bar code facing right

Press RUN button on the UCTA

Procedure complete
Low Volume Sample Processing

Start Here

Place sample in a Shared or DxC/UCTA rack for low volume sample containers (insert cups or 0.5 mL sample cup)*

Is sample programmed at the LIS?

Yes

Manually Assign
1. Select Samples from the workstation monitor
2. Select Racks F8
3. Enter Rack number
4. Enter SAMPLE ID in appropriate position field
5. Select OK

Place bar coded container in appropriate rack. Ensure that bar code label is visible through the rack slot. Verify tube is seated properly

No

Is there a readable bar code?

Yes

Place sample in the rack and position identified above

No

Open UCTA cover and place rack in the load tray with bar code facing right

Place sample in the rack and position identified above

1. Select Samples from the workstation monitor
2. Enter Rack/Pos if bar code is not available
3. Enter Sample ID
4. Select Chemistries
5. If needed, select STAT check box, Sample Type, Sample Comment and/or Demog F2
6. Select Next F10

Press RUN button on the UCTA

Procedure complete

*For samples with only DxC tests ordered:
- Use a validated DxC Only low volume sample container and rack. Load on UCTA load tray

For samples with only DxI tests ordered:
- Use a validated DxI Only low volume sample container and rack. Load directly on DxI SPU

Place sample in a Shared or DxC/UCTA rack for low volume sample containers (insert cups or 0.5 mL sample cup)*
Chapter 5
Instrument Commands

Instrument commands can be used to control functions of DxC and UCTA instrument components. Instrument commands include:

Home:
- Moves mechanical assemblies to their “home” positions and primes the system
- Recovers from a motion error
- Returns the DxC and/or UCTA to Standby from the Stopped state

Pause:
- Prevents initiation of new or additional tests at the DxC or UCTA
- Tests in process are completed
- Use to return the system to Standby as soon as possible

Shutdown:
- Use to reboot or safely shutdown the DxC
- Files are safely closed to prevent data corruption (failure to follow recommended procedure may result in data corruption)

Enable/Disable Modules:
- Use to enable/disable an individual MC cup module, the MC ISE, the entire MC side, the CC Photometer, the LPIA module, the CC lower reagent carousel, or the entire CC side of the system
- All programming for disabled modules is aborted. When a module is disabled the system will not run, prime, perform diagnostics, or maintenance procedures using that module
- The system may disable modules automatically after certain unrecoverable error conditions
- When a module is enabled, it will automatically prime

Unload All Racks:
- Use to unload racks from the DxC sample carousel, the UCTA sample carousel, or both
- Use when the screen displays racks on the Main Screen but the racks are not on the sample carousel following a system error

Other instrument commands include: 3 Stop Print, 5 Pause Waste B, and 6 Resume Waste B. Information about these commands may be found in the DxC Integrated Workstation IFU.
Home the DxC / UCTA

Select **Instr Cmd** from the workstation console

Select **1 Home**

Select one of the options:
- 1 DxC
- 2 UCTA
  OR
- 3 Both

The status of the selected system(s) changes to **Homing**

Note: If only one side of the DxC (MC or CC) is **Stopped**, the Home command operates on the side that is **Stopped**.

Homing is complete when the status displays **Standby** for the selected system(s)

**IMPORTANT**
If the **STOP** button is pressed immediately after selecting **Home**, wait at least 10 seconds and press the **STOP** button again to ensure that the system correctly reaches the **Stopped** state before proceeding with the Home command.
Pause the DxC / UCTA

Select Instr Cmd from the workstation console

Select 2 Pause

Note: The Pause command is available only if the system status is Running.

Select one of the options:
- 1 MC Only
- 2 CC Only
- 3 Both MC and CC
- 4 UCTA
- 5 MC, CC, and UCTA

The status of the selected system(s) will change to Pausing and return to Standby when in progress tests are completed

**IMPORTANT**
When Pausing the system, cuvette washing stops as soon the last result is available. Cuvettes may be left dirty. Do not request a Pause and leave the DxC sitting for a long period of time without washing the cuvettes.

See the IFU for more details on when to use Pause.
Shutdown the DxC Integrated Workstation

The DxC Integrated Workstation may require power down when:
- Part replacement procedures specify power to be turned off
- The lab power goes off
- The system is moved to a new location, or
- Recommended by a BCI specialist for troubleshooting purposes

Avoid system errors by following these recommendations:
- When one instrument component must be shut down, all three components (DxI, UCTA, DxC) of the DxC Integrated Workstation must be shut down
- Components should not be powered down independently
- Reboot is not recommended
- The DxI and DxC can be shut down and restarted simultaneously at their respective consoles
- The DxI instrument must be shut down before the DxI PC

Use the flowcharts on the following pages to shut down and restart the DxC Integrated Workstation.
Shut Down the DxC Integrated Workstations

### Shut Down the DxI

**Shut down the Instrument**
1. Verify the DxI system is in the *Ready* or *Not Ready* mode
2. Select **Configure F8** from the Main Menu of the DxI console
3. Select **PC Admin F7**
4. Select **System Admin F8** and then select **Shut Down Instrument F2**
5. Enter the system password and select **OK F1**
6. When the message displays to turn off the instrument select **OK F1**
7. Turn off the instrument power switch behind the lower right door of the DxI

**Shut down the PC**
1. Select **System Admin F8** and then select **Shut Down PC F1**
   - **IMPORTANT**: Do not select the **Shut down the instrument software** box
2. Select **Yes F1**
3. When the message displays that it is safe to turn off the computer, press and hold the DxI console power switch for at least 20 seconds, or until the green LED is off

   **Note**: If the software does not respond to shutting down the PC, press **Ctrl + Alt + Delete** on the keyboard to shut down the PC before turning off the computer power.

### Shut Down the UCTA

1. Press the UCTA power switch off (0 position)

### Shut Down the DxC

1. Verify the DxC system status is *Standby, Stopped,* or *Instrument Down*
   -- Clear any pop-up messages referring to the DxI and/or UCTA shutdown
2. Select **Instr Cmd** from the menu bar of the workstation console
3. Select **4 Shutdown**
4. Select **OK**. The Shutdown in Progress screen appears with the message
   "Please wait for further instructions. DO NOT TURN THE POWER OFF."
5. Select **Shutdown** when the Select Reboot of Shutdown dialog box appears
6. When “Shutdown Complete: It is now safe to reboot your computer” appears, turn off the power switch behind the far right door of the DxC instrument
7. Turn off the power to the workstation console computer by pressing and holding the power switch until the light goes out
Restart the DxC Integrated Workstation

**Restarting the DxI PC and Instrument**

1. Verify that the upper main covers of the DxI instrument are closed
2. Turn on the instrument power switch behind the lower right door of the DxI
3. Restart the DxI PC. Press the DxI console power switch until the green LED light comes on
4. Wait until the DxI console displays the DxI Main Menu
5. Verify the system mode returns to the Ready mode and no message is displayed in the system mode area. Note that this may take several minutes

**Restart the DxC**

1. Turn on the power to the workstation console computer
2. Turn on the power switch behind the far right door of the DxC instrument
3. The DxC system status displays *Startup* during the boot-up routine, followed by *Homing* of all mechanisms

**Restart the UCTA**

1. Verify the DxI is in the *Ready* mode and the DxC is in *Standby*
2. Turn the UCTA power switch to on (|) position
3. Verify the UCTA status returns to *Standby*

**NOTE**

Wait for the system to restore internal temperatures before processing samples. This may take 15-20 minutes, depending on the amount of time that power was off.

Resolve any errors before processing samples.
Enable / Disable Modules

Select **Instr Cmd** from the workstation console

Select 7 **Enable/Disable Modules**

Enable or Disable Module?

- **Enable**
  - Select the desired module button(s) to enable
  - Select **OK** to enable the module(s)

- **Disable**
  - Select the desired module button(s) to disable
  - Select **OK** to disable the module(s)
  - Select **OK** to confirm
Unload All Racks

Select **Instr Cmd** from the workstation console

Select 8 **Unload All Racks**

Select one of the options:
- 1 **DxC**
- 2 **UCTA**
  OR
- 3 **Both**

All racks in the selected sample carousel(s) will be removed to the DxC off-load area

Note: The status displays *Loading* for the selected system(s) during the Unload All command.
DxI Commands

The DxI system has commands that can be used to Initialize (home), Pause and Resume the DxI analyzer. These commands are initiated at the DxI console.

Initialize:
- Use to move mechanical assemblies to their "home" position
- Use to return the system to Ready from the Not Ready/Stopped mode

Pause:
- Prevents new or additional tests from initiating at the DxI instrument
- Any tests already in process are completed
- The DxI cannot be paused during a maintenance routine
- The system may enter the Paused mode if an error condition is detected

Resume:
- Use to restart the DxI system from the Paused mode
**Initialize the DxI**

Verify the DxI is in the *Not Ready* or *Ready* mode at the DxI console

Select **Diagnostics F7** from the Main Menu of the DxI console

Select **Initialize System F1**

Verify the following cleanout options are selected for a standard initialization:
- Sample Wheel – *Expired Only*
- Analytical Module – *In Progress Only*

Note: See the DxI Help system for more details on when to select the other initialization options.

Select **OK F1** to begin initialization

Note: The progress is displayed in the **Initialization status** fields. Initialization is complete when the system returns to the *Ready* mode.

Select **Yes F1** to confirm and exit the Initialize System window

**CAUTION**

Do not open the solid waste door during initialization. This will cancel the process and place the system in the *Not Ready* mode.
Pause the DxI

Select **Pause** at the DxI console

Select **Yes F1**

to the “Pause the system?” message

The DxI mode changes to *Paused*

Select **Resume** to restart the system
Chapter 6
Resources

Introduction
The following list will identify and describe resources available for your use.

Support Personnel

Technical Support (Hotline):
- Provides 24 hour phone support
- Contact at 1-800-854-3633

Applications Specialist:
- Provides installation support
- Your application specialist is ________________________ and (Name)
  can be reached at ________________________ (Phone)

Field Service Engineer:
- Installs the instrument
- Repairs and assists in maintaining your instrument
- Your Field Service Engineer is ________________________ and (Name)
  can be reached at ________________________ (Phone)

Instructions For Use and DxI Help System
The Instructions for Use (IFU) Manual includes basic operating instructions and maintenance guidelines for the UniCel DxC Integrated Workstation system. Detailed operation, maintenance, and troubleshooting instructions are included in this manual.

The DxC Integrated Workstation IFU is available on the workstation console through the Help menu bar icon. The DxI Help system is available at the DxI console through the Help button.

The reference materials listed on the next few pages are available for additional information.
Reference Materials

UniCel DxC Synchron Access Clinical System Integrated Workstations:

- UniCel DxC Synchron Access Clinical Systems Integrated Workstation *Instructions for Use Manual*
  - Provides operating instructions, maintenance instructions, and troubleshooting guidelines
  - Available to view and print through Help icon at the workstation console
  - Available at www.beckmancoulter.com and Product Manuals CD

- UniCel DxC Synchron Access Clinical Systems Integrated Workstations *UCTA Primary Tube Sample Template*
  - Use to establish adequate sample volume
  - Provided as a laminated sheet

UniCel DxI Access Immunoassay System:

- UniCel DxI Access Immunoassay System *Instructions for Use*
  - Contains basic operating and maintenance guidelines for the DxI analyzer
  - Available at www.beckmancoulter.com and CD

- UniCel DxI *Help System*
  - Contains detailed operating instructions, theory of operation, troubleshooting guidelines, and detailed maintenance instructions
  - Available to view and print through the Help button at the DxI console

- UniCel DxI *Sample Volume Guidelines*
  - Contains information for sample container volume requirements when loading samples on the DxI SPU
  - Provided as laminated sheets

- Access Immunoassay Systems *Assay Summary Tables* and individual *Assay Instructions for Use*
  - Contains specific assay information for the full range of assays available on the DxI analyzer
  - Available at www.beckmancoulter.com

- DxI *Installation Implementation Guide*
  - Provides an overview of the verification process and guidelines for precision evaluation
  - Provided as a hard copy manual
UniCel DxC Synchron Clinical Systems:

- UniCel DxC Synchron Clinical Systems *Reference Manual*
  - Contains detailed system description, operating instructions, theory of operation, system calibration, programming procedures, and quality control information
  - Available at [www.beckmancoulter.com](http://www.beckmancoulter.com) and Product Manuals CD

- Synchron Clinical Systems *Chemistry Information Sheets* and Synchron Clinical Systems *Chemistry Reference Manual*
  - Contains specific chemistry information for the full range of analytes available on the DxC system
  - Contains information about serum index
  - Available at [www.beckmancoulter.com](http://www.beckmancoulter.com)

- UniCel DxC Synchron Clinical Systems *Host Interface Specifications*
  - Provides necessary information to interface the DxC Integrated Workstation to a Laboratory Information System (LIS)
  - Includes Tables/Codes to interpret instrument codes printed on patient reports
  - Available at [www.beckmancoulter.com](http://www.beckmancoulter.com) and Product Manuals CD

- *Performance Verification Manual*
  - Assists in making a smooth transition integrating your new system into your daily routine
  - Includes guidelines for evaluating precision, accuracy, linearity, and method comparison
  - Available at [www.beckmancoulter.com](http://www.beckmancoulter.com)

- UniCel DxC Synchron Clinical Systems *Primary Tube Sample Template*
  - Use to verify adequate sample volume for the DxC
  - Provided as a laminated sheet

- UniCel DxC Synchron Clinical Systems *Reagent Preparation Quick Reference*
  - Provides information on reagents that require preparation
  - Provided as a laminated sheet
Chapter 7
In-Lab Training Competency Checklist

Purpose

The following In-Lab Training Competency Checklist may be used to document the in-lab training of laboratory staff on the operation of the DxC Integrated Workstation. As each operator is trained, both the trainer and the trainee initial and date the documentation form.
<table>
<thead>
<tr>
<th>Task</th>
<th>Resource</th>
<th>How Measured?</th>
<th>Achieved?</th>
<th>N/A</th>
<th>Date</th>
<th>Trainee Initial</th>
<th>Trainer Initial</th>
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<tbody>
<tr>
<td><strong>System Overview</strong></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>• Identify DxI Hardware Components</td>
<td>DxI Online Help (Main Menu) → Help → System Overview → Instrument Overview → Show me the UniCel DxI Instrument and System Console</td>
<td>❑ Direct Observation, ❑ Test, ❑ Other</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
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<tr>
<td>• Identify UCTA Components</td>
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<tr>
<td>• Identify DxC Modular Chemistry (MC) Components</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 1: System Description</td>
<td>❑ Direct Observation, ❑ Test, ❑ Other</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
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<tr>
<td>• Identify DxC Cartridge Chemistry (CC) Components</td>
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<td><strong>Software Overview</strong></td>
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<tr>
<td>• Workstation Console</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 2: Software Description</td>
<td>❑ Direct Observation, ❑ Test, ❑ Other</td>
<td>❑</td>
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<tr>
<td>• DxI Console</td>
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<tr>
<td><strong>Daily Start Up</strong></td>
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</tr>
<tr>
<td>• Determine supply / reagent status for DxI</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 3: Daily Start Up</td>
<td>❑ Direct Observation, ❑ Test, ❑ Other</td>
<td>❑</td>
<td>❑</td>
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<tr>
<td>• Determine supply / reagent status for UCTA</td>
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<td>• Determine supply / reagent status for DxC</td>
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### Competency Checklist

#### UniCel DxC Synchron Access Clinical System Integrated Workstations

<table>
<thead>
<tr>
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<th>Achieved?</th>
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<th>Date</th>
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<th>Trainer Initial</th>
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<tr>
<td>• Load supplies/reagents on DxI</td>
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<td>• Load supplies/reagents on UCTA</td>
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<td>• Load supplies/reagents on DxC</td>
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<td>• Clear racks</td>
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#### Calibration

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<th>Trainer Initial</th>
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<tr>
<td>• Determine calibration status for DxI immunoassays</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual</td>
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<td>• Determine calibration status for DxC chemistries</td>
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<td>• Program and process calibration for DxI immunoassays</td>
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<tr>
<td>• Program and process calibration for DxC chemistries</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual</td>
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#### Sample Processing

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<th>Trainer Initial</th>
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<tbody>
<tr>
<td>• Identify sample requirements</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual</td>
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<tr>
<td>• Determine correct sample rack/container for sample processing at workstation console</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual</td>
<td>Direct Observation</td>
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## Competency Checklist

### UniCel DxC Synchron Access Clinical System Integrated Workstations

<table>
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<tr>
<th>Task</th>
<th>Resource</th>
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<th>Date</th>
<th>Trainee Initial</th>
<th>Trainer Initial</th>
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<tbody>
<tr>
<td>• Program and process routine and STAT patient samples at workstation console</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 4: Sample Programming and Processing</td>
<td>❑ Direct Observation ❑ Test ❑ Other ________</td>
<td>❑ ❑ ❑</td>
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<td>• Locate completed test results</td>
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<td>❑ Direct Observation ❑ Test ❑ Other ________</td>
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<tr>
<td>• Program and process QC at workstation console</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 5: Quality Control</td>
<td>❑ Direct Observation ❑ Test ❑ Other ________</td>
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<td>• Define Quality Control</td>
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<td>• QC Results Management</td>
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<tr>
<td>• Perform Daily maintenance on DxI</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 3: Daily Start Up</td>
<td>❑ Direct Observation ❑ Test ❑ Other ________</td>
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<tr>
<td>• Perform Weekly maintenance on DxI (if running HIV assay)</td>
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<td>• Perform Twice Weekly and Weekly maintenance on DxC</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 12: Maintenance</td>
<td>❑ Direct Observation ❑ Test ❑ Other ________</td>
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<td>• Perform Twice-Monthly maintenance on UCTA</td>
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<td>• Perform Monthly maintenance on DxC</td>
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## UniCel DxC Synchron Access Clinical System Integrated Workstations

### Competency Checklist

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<th>Task</th>
<th>Resource</th>
<th>How Measured?</th>
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<td>Perform 2-Month Maintenance on DxC</td>
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<td>Perform 3-Month Maintenance on DxC</td>
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<td>Perform 4-Month Maintenance on DxC</td>
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<td>Perform 6-Month Maintenance on DxC</td>
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<td>Perform Yearly Maintenance on UCTA</td>
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<td>Perform 5,000 Test Interval Maintenance on DxI</td>
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<td>Perform 10,000 Test Interval Maintenance on DxI</td>
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### Miscellaneous

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<tr>
<td>Instrument Setup at the workstation console</td>
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<td>Quality Control Setup/Definition at the workstation console</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual</td>
<td>Direct Observation</td>
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<tr>
<td>Quality Control Results Management at workstation console</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual</td>
<td>Direct Observation</td>
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## UniCel DxC Synchron Access Clinical System Integrated Workstations

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<th>Task</th>
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<th>Date</th>
<th>Trainee Initial</th>
<th>Trainer Initial</th>
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</thead>
<tbody>
<tr>
<td>Operate system in Independent Mode (DxC, UCTA or DxI non-operational)</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 9: Independent Mode</td>
<td>❏ Direct Observation</td>
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<tr>
<td>Power down/restart DxI, UCTA and DxC</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 8: System Status, Instrument Commands, and Utilities</td>
<td>❏ Direct Observation</td>
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<td>Initialize DxI</td>
<td>DxI Online Help (Main Menu) → Help Topics → Contents Tab → Reference Information → Diagnostics → Initialize System</td>
<td>❏ Direct Observation</td>
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<tr>
<td>Home UCTA and DxC</td>
<td>DxC Integrated Workstation Instructions For Use (IFU) Manual → Chapter 8: System Status, Instrument Commands, and Utilities</td>
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Chapter 8
DxC Integrated Workstation Competency Exercise

Instructions
The competency exercise should be completed at the end of the in-lab training session. All materials supplied with the instrument or used during the training may be used to complete this exercise. Save all reports generated during the exercise. Submit all printed reports and this exercise to your supervisor and/or your Beckman Coulter Applications Specialist.
Instrument Overview

1. As a sample processing manager, the UniCel Closed Tube Aliquotter (UCTA) will create an ____________ for processing on the DxI and __________ the sample container to the DxC for further processing.

2. The DxC is composed of two sides. Which side performs rapid analysis for specific chemistries?
   ___________ ___________ (___ ___) side

3. On the MC side of the DxC analyzer, sample is delivered to the _________________ for analysis of electrolytes (sodium, potassium, chloride, CO2, and calcium).

4. The CC side of the DxC analyzer delivers reagent from cartridges stored in a refrigerated compartment that houses _____ reagent cartridges.

5. The DxI system utilizes _________________ technology.
6. The DxI console is used for DxI ________________, ________________, diagnostics and in independent mode operations.

7. Label each circle on the picture below with the letter corresponding to its description:
   a  DxI Console Status
   b  System Status
   c  Reagent/Calibration Menu Bar Icon
   d  Sample Status Icons

8. What tab would you select to view samples on the UCTA sample carousel? ________________

9. On the workstation console, the icon with the drawing of the wrench takes the user to the ________________ menu.
10. Which icon would you use at the workstation console to print a supply status for the entire system? ________________

11. Place a number before each task below indicating the recommended order they should be performed as part of a Daily Start Up:

   ____  Process Quality Control
   ____  Print/View Reagent, Calibration, and Supply Status
   ____  Perform Daily Maintenance
   ____  Calibrate required tests
   ____  Load Reagents and Supplies

12. The Daily Clean is requested at the ____________ console, using the ________________ F1 menu.

13. If your lab processes the ________ assay you should run a Special Clean instead of a Daily Clean.

14. What supplies are required for UCTA operation? ________________ and ________________
15. When calibrating DxC chemistries, what function key do you use to view the calibrator load list? _________________

16. DxI calibration is requested at the _________ console and loaded on the DxI _________ _______________ __________ (SPU).

17. Perform a Daily Start Up on your DxC Integrated Workstation. Keep all reports and show them to your supervisor and/or Beckman Coulter representative when the Daily Start Up is completed.

18. If you are processing a validated capped sample, you should remove __________ __________ using a cotton tipped swab moistened with DI water.

19. What do you use to determine adequate sample volume?

______________________________

20. DxC/UCTA sample racks can be loaded on the UCTA load tray and used to create sample vessels (SVs) for DxI testing.

True  [ ]  False  [ ]
Sample Processing, continued

21. Manually program and process samples using the following information:

Note: You may use any material you have available for the samples.

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Sample Type</th>
<th>Priority</th>
<th>Tests</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test 1</td>
<td>Serum</td>
<td>Routine</td>
<td>NA, K, CL, CO2, GLUCm</td>
<td>Name: Test Sample Age: 3 yrs</td>
</tr>
<tr>
<td>Test 2</td>
<td>CSF</td>
<td>STAT</td>
<td>GLUCm</td>
<td>N/A</td>
</tr>
<tr>
<td>Test 3</td>
<td>Timed Urine</td>
<td>Routine</td>
<td>GLUCm</td>
<td>Volume: 1340 mL</td>
</tr>
</tbody>
</table>

Note: You may use any material you have available for the samples.

22. Show the reports to your supervisor and/or Beckman Coulter representative.

Instrument Commands

23. Draw a line between the Instrument Command you would use to perform the described function:

<table>
<thead>
<tr>
<th>Instrument Command</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td>Use to power off the DxC</td>
</tr>
<tr>
<td>Pause</td>
<td>Use to remove racks from the Main Menu screen that are not present on the sample carousel</td>
</tr>
<tr>
<td>Shutdown</td>
<td>Use to turn on the Glucose module</td>
</tr>
<tr>
<td>Enable Module</td>
<td>Use to recover from a motion error</td>
</tr>
<tr>
<td>Unload All Racks</td>
<td>Use to complete in progress tests but to prevent any new tests from starting</td>
</tr>
</tbody>
</table>

24. When the DxC is powered down the DxI and UCTA must also be powered down:

True [ ] False [ ]

Completion

25. Give all reports and answers to the competency questions to your supervisor and/or Beckman Coulter representative for comparison to the Answer Key.
Answer Key

Instrument Overview

1. As a sample processing manager, the UniCel Closed Tube Aliquotter (UCTA) will create an aliquot for processing on the DxI and transfer the sample container to the DxC for further processing.

2. The DxC is composed of two sides. Which side performs rapid analysis for specific chemistries?
   Modular Chemistry (MC) side

3. On the MC side of the DxC analyzer, sample is delivered to the electrolyte injection cup (EIC) for analysis of electrolytes (sodium, potassium, chloride, CO2, and calcium).

4. The CC side of the DxC analyzer delivers reagent from cartridges stored in a refrigerated compartment that houses 59 reagent cartridges.

5. The DxI system utilizes chemiluminescent technology.
**Software Overview**

6. The DxI console is used for DxI *calibration*, *maintenance*, diagnostics and in independent mode operations.

7. Label each circle on the picture below with the letter corresponding to its description:
   - a. DxI Console Status
   - b. System Status
   - c. Reagent/Calibration Menu Bar Icon
   - d. Sample Status Icons

8. What tab would you select to view samples on the UCTA sample carousel? **UCTA Tab**

9. On the workstation console, the icon with the drawing of the wrench takes the user to the **Utilities** menu.
10. Which icon would you use at the workstation console to print a supply status for the entire system? Rghts/Cal

11. Place a number before each task below indicating the recommended order they should be performed as part of a Daily Start Up:

5  Process Quality Control
1  Print/View Reagent, Calibration, and Supply Status
2  Perform Daily Maintenance
4  Calibrate required tests
3  Load Reagents and Supplies

12. The Daily Clean is requested at the DxI console, using the Sample Manager F1 menu.

13. If your lab processes the Vitamin B12 assay you should run a Special Clean instead of a Daily Clean.

14. What supplies are required for UCTA operation?

Wash Buffer and Auto-Gloss
15. When calibrating DxC chemistries, what function key do you use to view the calibrator load list?  **List F5**

16. DxI calibration is requested at the DxI console and loaded on the DxI **Sample Presentation Unit** (SPU).

17. Perform a Daily Start Up on your DxC Integrated Workstation.
   Keep all reports and show them to your supervisor and/or Beckman Coulter representative when the Daily Start Up is completed.

18. If you are processing a validated capped sample, you should remove **visible blood** using a cotton tipped swab moistened with DI water.

19. What do you use to determine adequate sample volume?
   **UCTA Primary Tube Sample Template**

20. DxC/UCTA sample racks can be loaded on the UCTA load tray and used to create sample vessels (SVs) for DxI testing.
   True [✓] False [ ]
21. Manually program and process samples using the following information:

Note: You may use any material you have available for the samples.

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22. Show the reports to your supervisor and/or Beckman Coulter representative.

23. Draw a line between the Instrument Command you would use to perform the described function:

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24. When the DxC is powered down the DxI and UCTA must also be powered down:

True  [✓]  False

25. Give all reports and answers to the competency questions to your supervisor and/or Beckman Coulter representative for comparison to the Answer Key.
This certificate signifies that

has completed the In-Lab Training course on the operation of the

UniCel DxC Integrated Workstation

Beckman Coulter Representative

Date