

## BIO-RAD MONTHLY QC PROCEDURE

### Safety Message

Use universal precautions when handling patient samples or human source quality control material.

### Purpose

To outline the procedure for the monthly extraction of QC data from analyzers, Remisol or logs, and entry of QC summary data into Bio-Rad web based QC program ([www.qcnet.com](http://www.qcnet.com)).

### Policy

- QC chart and summary data of previous month:
  - Extract from analyzer if on-board QC storage exist.
  - For analyzers without on-board QC storage, data is extracted from Remisol (Extended Quality Control files) data base or logs.
- Extracted QC data is reviewed by the section manager.
- Summary data is entered into Unity Web™ 2.0 program ([www.qcnet.com](http://www.qcnet.com)) before the 7<sup>th</sup> day of the month for peer data comparison.
- Generate and review the QC report for the previous month around the 15<sup>th</sup> of the current month.

### QC DATA EXTRACTION:

**Procedure:**  
**DXC800**  
**QC Data**  
**Summary and**  
**Chart**  
**Extraction**

Step	Action
1	From the main menu click on the QC icon.
2.	Select the control name of the file to be extracted: <ul style="list-style-type: none"> <li>• 1LC1</li> <li>• 1LC2</li> <li>• PED</li> <li>• U1</li> <li>• U2</li> <li>• CSF L-1</li> <li>• CSF L-2</li> <li>• AMM/ETOH L-1</li> <li>• AMM/ETOH L-3</li> <li>• BR1 MULTIQUAL-1</li> <li>• BR3 MULTIQUAL-3</li> <li>• CM1</li> <li>• CM3</li> </ul>
3.	Click on Summary (F6)
4.	Enter QC Date Range
5	Click "OK"
6.	Click on Chart (F7)
7.	Click "OK"
8.	Repeat steps 2 to 7 until all BioRad QC has been printed for the month.


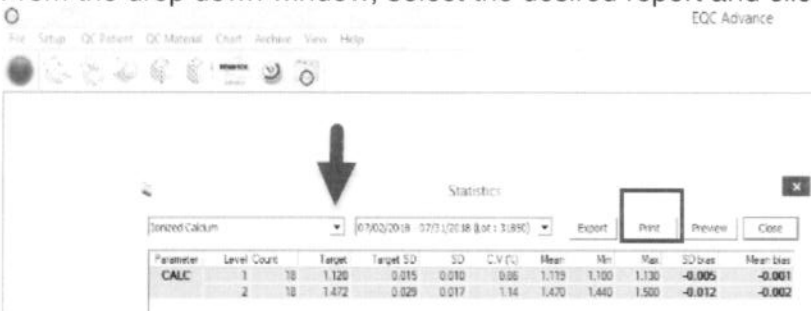
## BIO-RAD MONTHLY QC PROCEDURE

**Procedure**  
**Dxl600**  
**QC Data**  
**Summary and**  
**Chart**  
**Extraction**

Step	Action
1	From the main menu click on the QC icon.
2.	Click on the QC and level (one file at a time): <ul style="list-style-type: none"> <li>• CM1:BNP2</li> <li>• CM3:BNP</li> <li>• CM1:CKMB</li> <li>• CM3:CKMB</li> <li>• CM1:TnIDx</li> <li>• CM3:TnIDx</li> <li>• HCG5-Q1:HCG5</li> <li>• HCG5-Q2:HCG5</li> <li>• HCG5-Q3:HCG5</li> <li>• S-IMMQC-1:PTHIO</li> <li>• S-IMMQC-2:PTHIO</li> <li>• S-IMMQC-3:PTHIO</li> </ul>
3.	At QC Chart and Data screen: <ul style="list-style-type: none"> <li>• Filter (F1)               <ul style="list-style-type: none"> <li>○ Enter date range</li> </ul> </li> <li>• Print:               <ul style="list-style-type: none"> <li>○ Chart-OK (F1)</li> </ul> </li> </ul>
4.	Repeat Step #2 to #3 until all QC files are printed.

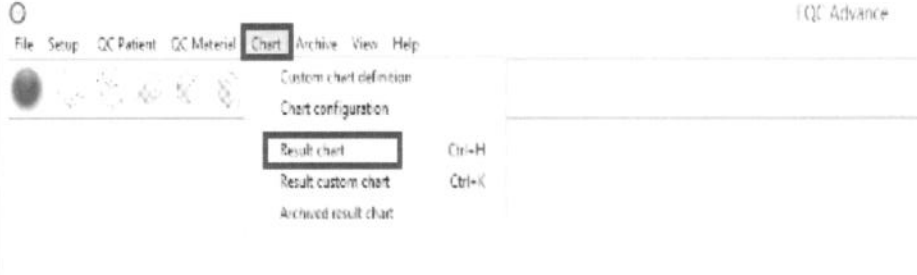
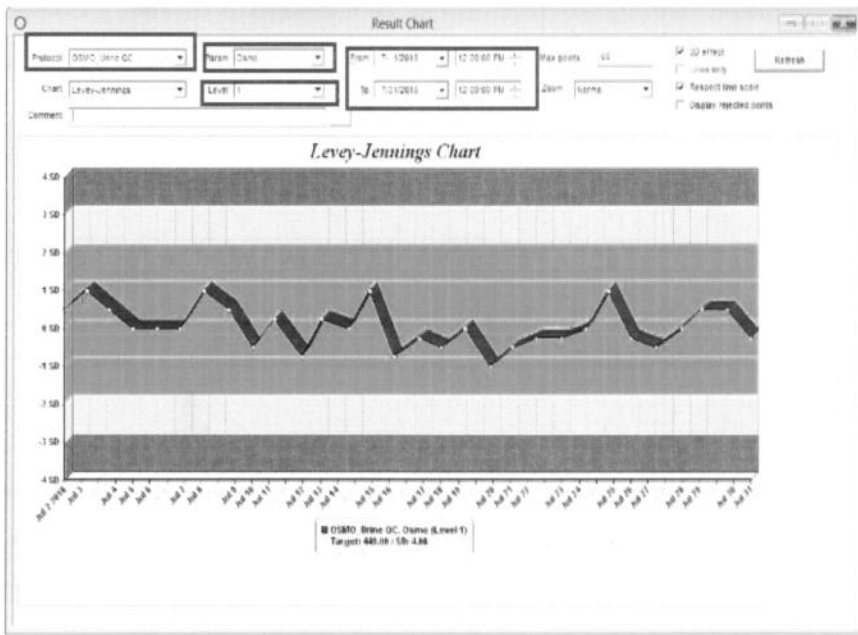
## BIO-RAD MONTHLY QC PROCEDURE

**Procedure**  
**EQC Data**  
**Summary**  
**Extraction**

Step	Action																																			
1.	<p>From the QC Material Menu, Select Statistics</p>  <p>The screenshot shows the 'QC Material' menu with the following options: New, Open, Cus Programming (Ctrl+Q), Error points (Ctrl+J), Manual collection, Time out management, 6-Sigma Rule Definition, Results by Parameter (Ctrl+R), Results by Run (Ctrl+O), Last collected results (Ctrl+L), QC Review, Statistics (Ctrl+S), and Date-to-date Statistics.</p>																																			
2.	<p>From the drop down window, select the desired report and click print.</p>  <p>The screenshot shows the 'Statistics' window with a dropdown menu for 'Ionized Calcium' and a date range of '07/02/2018 - 07/31/2018 (Lot: 31890)'. The 'Print' button is highlighted with a red box. A black arrow points to the dropdown menu.</p> <table border="1" data-bbox="695 1360 1344 1423"> <thead> <tr> <th>Parameter</th> <th>Level</th> <th>Count</th> <th>Target</th> <th>Target SD</th> <th>SD</th> <th>C.V (%)</th> <th>Mean</th> <th>Min</th> <th>Max</th> <th>SD bias</th> <th>Mean bias</th> </tr> </thead> <tbody> <tr> <td rowspan="2">CALC</td> <td>1</td> <td>10</td> <td>1.120</td> <td>0.015</td> <td>0.010</td> <td>0.06</td> <td>1.119</td> <td>1.100</td> <td>1.130</td> <td>-0.005</td> <td>-0.001</td> </tr> <tr> <td>2</td> <td>10</td> <td>1.472</td> <td>0.029</td> <td>0.017</td> <td>1.14</td> <td>1.470</td> <td>1.440</td> <td>1.500</td> <td>-0.012</td> <td>-0.002</td> </tr> </tbody> </table>	Parameter	Level	Count	Target	Target SD	SD	C.V (%)	Mean	Min	Max	SD bias	Mean bias	CALC	1	10	1.120	0.015	0.010	0.06	1.119	1.100	1.130	-0.005	-0.001	2	10	1.472	0.029	0.017	1.14	1.470	1.440	1.500	-0.012	-0.002
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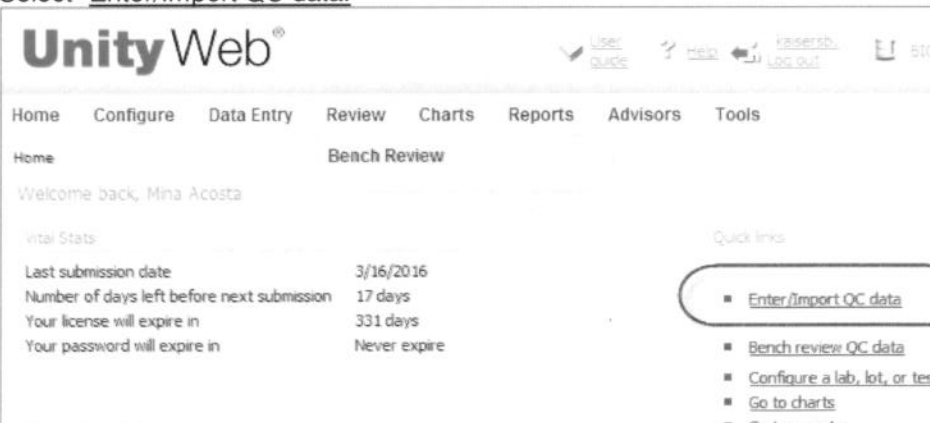
Procedure  
 EQC  
 Chart Data  
 Printing

Step	Action
1	<p>Select Chart then Result chart</p>  <p>The screenshot shows a software menu with 'Chart' selected. The 'Result chart' option is highlighted with a black box. Other options include 'Custom chart definition', 'Chart configuration', 'Result custom chart', and 'Archived result chart'. Keyboard shortcuts 'Ctrl-H' and 'Ctrl-K' are also visible.</p>
2	<p>Select the protocol to print, enter the desired level, date, time and click print icon.</p>  <p>The screenshot shows the 'Result Chart' window. The 'Protocol' is 'OSMD Urine GC', 'Osmo (Level 1)'. The 'Print' button is highlighted. The chart is a Levey-Jennings chart with a target of 440.00 / 5h 4.00. The y-axis ranges from -4.50 to 4.50. The x-axis shows dates from 06/17/08 to 06/27/08.</p>

## BIO-RAD MONTHLY QC PROCEDURE


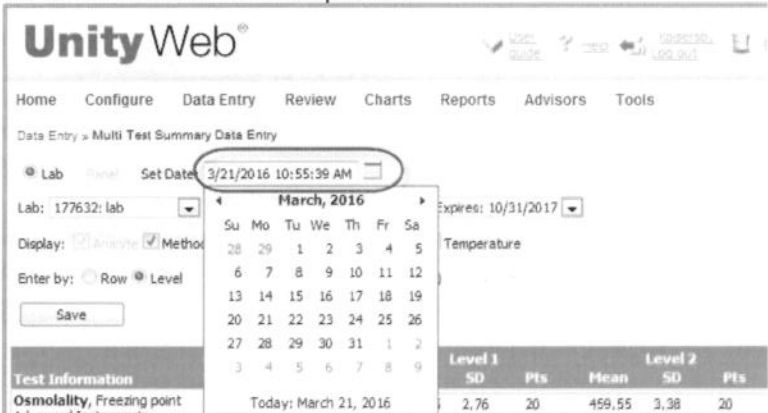
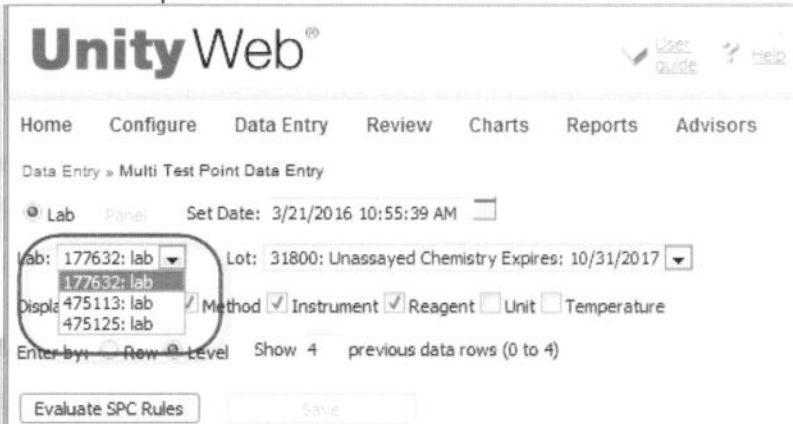
### BIO-RAD QC DATA ENTRY:

**Procedure**  
**Bio-Rad**  
**Data Entry**

Step	Action
1	<p>Log on to UnityWeb™</p> <ul style="list-style-type: none"> <li>• <a href="http://www.qcnet.com">http://www.qcnet.com</a></li> <li>• Type in your Login ID and Password</li> <li>• Click Login</li> <li>• Point to Unity™ Interlab and then click UnityWeb™ 2.0</li> </ul> 
2.	<p>Type in User and Password:</p> 
3.	<p>Select "Enter/Import QC data:</p> 

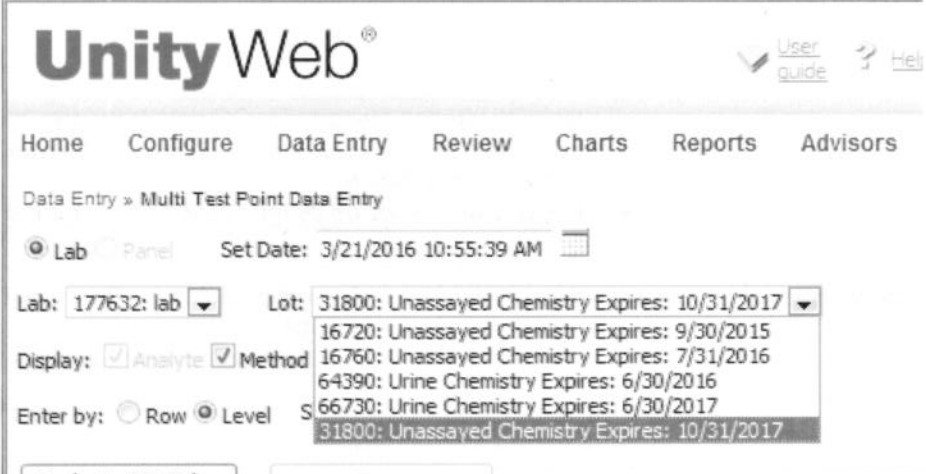
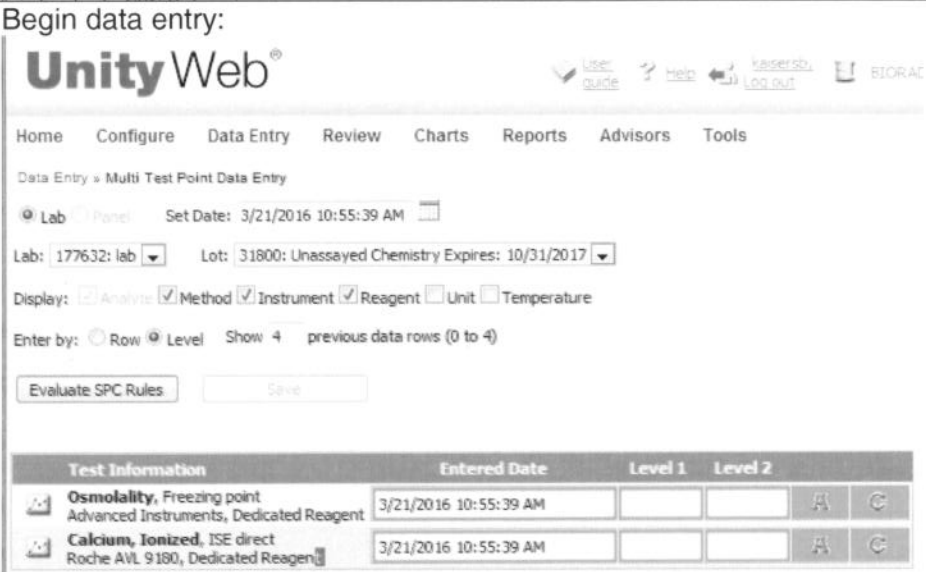
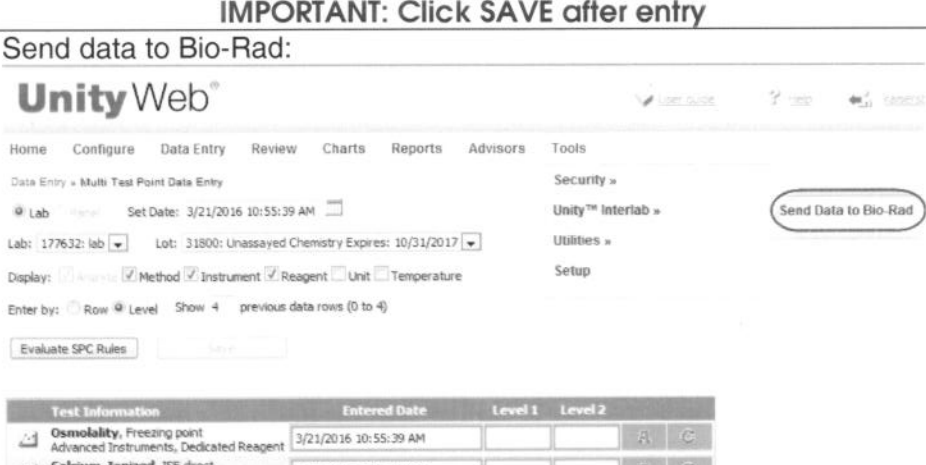
## BIO-RAD MONTHLY QC PROCEDURE

**Procedure**  
**Bio-Rad**  
**Data Entry**

Step	Action												
4.	Select "Multi Test Summary Data Entry" 												
5.	Set date of data accumulation period: 												
6.	Select Lab specific number:  <p>Note:</p> <table border="1" data-bbox="609 1638 1331 1837"> <tbody> <tr> <td>177632</td> <td>Model 3320 Osmometer: Blood and Urine Osmo</td> </tr> <tr> <td></td> <td>Roche ACL 9180: Ionized CA</td> </tr> <tr> <td>475113</td> <td>DXC800 #1</td> </tr> <tr> <td></td> <td>DxI600 #1</td> </tr> <tr> <td>475125</td> <td>DXC800#2</td> </tr> <tr> <td></td> <td>DxI600 #2</td> </tr> </tbody> </table>	177632	Model 3320 Osmometer: Blood and Urine Osmo		Roche ACL 9180: Ionized CA	475113	DXC800 #1		DxI600 #1	475125	DXC800#2		DxI600 #2
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## BIO-RAD MONTHLY QC PROCEDURE

Procedure  
 Bio-Rad  
 Data Entry

Step	Action												
7.	<p>Select QC lot #:</p> 												
8.	<p>Begin data entry:</p>  <table border="1"> <thead> <tr> <th>Test Information</th> <th>Entered Date</th> <th>Level 1</th> <th>Level 2</th> </tr> </thead> <tbody> <tr> <td><b>Osmolality, Freezing point</b> Advanced Instruments, Dedicated Reagent</td> <td>3/21/2016 10:55:39 AM</td> <td></td> <td>A C</td> </tr> <tr> <td><b>Calcium, Ionized, ISE direct</b> Roche AVL 9180, Dedicated Reagent</td> <td>3/21/2016 10:55:39 AM</td> <td></td> <td>A C</td> </tr> </tbody> </table> <p><b>IMPORTANT: Click SAVE after entry</b></p>	Test Information	Entered Date	Level 1	Level 2	<b>Osmolality, Freezing point</b> Advanced Instruments, Dedicated Reagent	3/21/2016 10:55:39 AM		A C	<b>Calcium, Ionized, ISE direct</b> Roche AVL 9180, Dedicated Reagent	3/21/2016 10:55:39 AM		A C
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9.	<p>Send data to Bio-Rad:</p> 												

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### Procedural Notes

- Contact person for issues with BioRad site is Chris Kanis. He can be reached by phone or e-mail:
    - 1-800-854-6737. X1270, #2
    - [Chris\\_Kanis@Bio-Rad.com](mailto:Chris_Kanis@Bio-Rad.com)
  - Unity™ Interlab Reports for QC data from previous month can be generated from the <http://www.qcnet.com/QCNET/UnityReports.aspx> site around the 15th of the current month.
  - Reports are reviewed by the section manager monthly.
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### References

- UnityWeb™ 2.0.Reference Guide for Easy QC Data Management.Bio-Rad Laboratories.June 2008.
  - EQC User Guide for Remisol Advance version 1.9, March 2013.
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### Authors

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  - Jay Raymund Castaneto, MT, BSMT
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## BIO-RAD MONTHLY QC PROCEDURE

### Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Laboratory Operations Director Reviewed/Date	Laboratory Medical Director Reviewed/Date	Date change implemented
<b>New</b>		A. Dabir 8-15-07	N. Muneno 08-14-07	R.H. Doshi, MD 08-26-07	08-26-07
<b>Major</b>	Updated: <ul style="list-style-type: none"> <li>• Lab # reflecting change in analyzers.</li> <li>• Analyzer list: Replaced Access2 analyzers with DxI600s</li> <li>• Bio-Rad contact: Replaced Beverly Street (Bio-Rad tech support contact) with Chris Kanis.</li> <li>• Procedure to reflect version change to QCWeb® 2.0</li> </ul>	M.Acosta 03-21-16	J.Wolf 03-31-16	S.Wirio MD 04-14-16	04-14-16
<b>Major</b>	Updated: <ul style="list-style-type: none"> <li>• Removed LMS procedure steps for QC data and summary extraction.</li> <li>• Added EQC procedure steps for QC data and summary extraction.</li> </ul>	 8-6-18	 8-7-18	 8/7/18	8/7/18

