

PROGRAM Standard Operating Procedure – Laboratory Services	
Title: QCM10000 Core Laboratory Quality Control	Policy Number: 15-202-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date:	Next Review Date:
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

**GUIDING PRINCIPLE:**

Running Quality Controls in a laboratory ensures accuracy, consistency, and reliability in our processes, testing and patient results. This is achieved by implementing systematic procedures, monitoring performance and by investigating and correcting any issues that arise. When quality control is outside of expected limits, all testing involved will be stopped until the issue is resolved.

**PURPOSE/RATIONALE:**

Core Laboratory Quality Control testing is performed to ensure that patient results consistently meet the highest standards of quality.

**DEFINITIONS:**

QC- Quality Control  
LIS- Laboratory Information System  
BSC- Biological Safety Cabinet

**SCOPE/APPLICABILITY:**

This procedure applies to Medical Laboratory Technologists (MLT's) who will be performing this procedure.

**SPECIAL SAFETY PRECAUTIONS:**

- Ensure proper Personal Protective Equipment (PPE) is used such as gloves, lab gowns and eye protection when possible exposure to splashes.
- Ensure all samples are treated following routine practices and assume all products as potentially infectious.

### **Vitros 7600**

- Bio-Rad Liquichek Unassayed Controls Level 1 and 2 will be performed daily on each shift
- Bio-Rad Liquichek Elevated CRP Control Level 1 will be performed daily on each shift
- Bio-Rad Liquichek Lipid Controls Level 2 will be performed daily on each shift
- Bio-Rad Liquichek Pediatric Controls Level 2 will be performed daily on each shift
- Bio-Rad Liquichek Immunoassay Plus Controls Level 1, 2 and 3 will be performed daily on each shift
- Bio-Rad Liquichek Cardiac Plus Controls Level 1, 2 and 3 will be performed daily on each shift
- Bio-Rad Liquichek Spinal Fluid Controls Level 1 and 2 will be performed daily on each shift
- Bio-Rad Liquichek Diabetes Controls Level 1 and 2 will be performed daily on each shift
- Bio-Rad Urine Chemistry Controls Level 1 and 2 will be performed daily on each shift
- Bio-Rad Viroclear Control will be performed daily on each shift
- Bio-Rad Virotrol I Control will be performed daily on each shift
- Bio-Rad Virotrol II Control will be performed daily on each shift
- Bio-Rad Virotrol Syphilis LR-A Control will be performed daily on each shift

### **Sysmex XN-1000**

- XN Check Controls Level 1, 2 and 3 will be performed on each shift daily
- XN Check BF Controls Level 1 and 2 will be performed daily

### **Siemens CA660**

- PT and PTT testing requires performing the Dade Ci-Trol Controls, Level 1, 2 and 3 every 8 hours
- D-Dimer testing requires performing the Innovance D-Dimer Control, Levels 1 and 2 every 8 hours
- Fibrinogen testing requires performing the Dade Data-Fi Abnormal Control and the Dade Ci-Trol Level 1 Control every 8 hours

### **Clinitek Advantus**

- Quantimetrix Dropper Level 1 and 2 Urine Controls will be performed daily. Refer to **URN10100 Clinitek Advantus Quality Control**

### **Excyte M**

- Accu-Sed Plus Normal and Abnormal Controls are performed every 24 hours, when patient testing is required

### **ABL800**

- Autocheck 6+ Level 1, 2 and 3 will be performed internally every 8 hours

### **ABL90**

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- Internal QC will be run every 8 hours

#### **Osmo1- Automated Osmometer**

- Clinitrol 290 Standard will be performed with each series of tests
- Protinol Level 1, 2 and 3 Controls will be performed every 24 hours
- Renol Level 1 and 2 Urine Controls will be performed every 24 hours

#### **QuickStep Plus HCG Urine Pregnancy Test**

- An Internal Procedural Control is included in the test
- Quantimetrix Dropper Level 1 and 2 Urine Controls will be performed once per week and with each new kit lot number/shipment. Refer to **URN30100**

#### **QuickStep Plus HCG Urine Pregnancy Test**

#### **SureStep™ Urine Test Drug Screen Dip Card**

- An Internal Procedural Control is included in the test
- Liquichek™ Qualitative Urine Toxicology Controls are performed each time a new box is opened. Refer to **URN30200 SureStep™ Urine Test Drug Screen Dip Card**

#### **Binax NOW RSV**

- An Internal Procedural Control is included in the test
- Quality Control will be performed when each new box is opened using the positive and negative control swabs included in the kit. Refer to **URN30300 Binax NOW RSV Procedure**

#### **Pulse Scientific Monogen Latex Testing**

- IM Positive and IM Negative Controls are included with each kit and will be performed with each series of tests. Refer to **URN 40100 Pulse Scientific Monogen Latex Testing**

#### **Quality control records audit procedure**

- The Technical Supervisor, Core Lab reviews completed quality control records in TQC on a weekly basis
- The Technical Supervisor, Core Lab reviews monthly reports generated through our QC Programs, Bio-Rad Unity, Sysmex Insight and Siemens QAP
- Completed quality control records in TQC are kept indefinitely, weekly reviews of QC are stored in the large filing cabinet 2 years and completed reviews of monthly QC results are scanned onto the Lab Tech II-Safety shared drive

#### **External Quality Assurance Programs-EQAS and CAP**

- The Core Laboratory participates in External Quality Assessment programs (EQA) administered by Bio-Rad (EQAS) and the College of American Pathologists (CAP).
- Evaluation reports and Participants Summary's will be saved onto the Lab Tech II- Safety shared drive
- EQA specimens that are completed by MLTs will be documented on QUA30310-Laboratory Competence Assessment Form.

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### **Temperature and humidity monitoring**

- At the beginning of the 0630 shift, perform temperature checks within the Core Laboratory
- Thermometers are replaced and verified annually and recorded on QUA40493-Thermometer Log

### **Microscopes**

- Check Kohler illumination daily. Refer to **MIC61120-Kohler Illumination Job Aid**
- All microscopes receive annual preventative maintenance

### **Biological safety cabinets (BSC)**

- Perform daily, weekly and bi-annual maintenance as required.
- BSC's are inspected, tested, and certified annually

### **TROUBLESHOOTING:**

Refer to **QCM10100 Quality Control Troubleshooting Procedure** to resolve any quality controls issues that may arise. Document all work completed using the **QCM10300 Quality Control Troubleshooting Checklist**.

### **CROSS-REFERENCES:**

URN10100 Clinitek Advantus Quality Control  
URN30100 QuickStep Plus HCG Urine Pregnancy Test  
URN30200 SureStep™ Urine Test Drug Screen Dip Card  
URN30300 Binax NOW RSV Procedure  
URN 40100 Pulse Scientific Monogen Latex Testing  
QUA30310-Laboratory Competence Assessment Form  
QUA40493-Thermometer Log  
MIC61120 Kohler Illumination Job Aid  
QCM10100 Quality Control Troubleshooting Procedure  
QCM10300 Quality Control Troubleshooting Checklist

### **REFERENCES:**

Siemens Application Sheets and Package Inserts

CLSI QMS12-A:2010 Development and use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality, 1<sup>st</sup> Edition

### **APPROVAL:**

April 17, 2025

Date

  
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Director, Laboratory and Diagnostic Imaging Services

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	10 Mar 2025	Initial Release	L. Howlett