Glucose Meter Proficiency Testing CAPT_QUA_0700

Purpose:

- The purpose of this document is how to perform proficiency testing on the Nova glucose meters.
- All POCT is evaluated using a formal proficiency testing program or by an alternate means of assessment.
- POCT PT assessment is examined by personnel who routinely examine patient samples. Proficiency testing or alternate assessment is performed by POCT operators.
- Proficiency testing or alternate assessment occurs at least twice per year.

PT Frequency

DAP Provisionally Accredited Facility

DAP reportable measurands	All services	Minimum two samples and one test event prior to full DAP assessment
Non-reportable measurands		

DAP Accredited Facility

DAP reportable measurands	All services	Minimum four samples per year Minimum two testing events per year
Non-reportable measurands		

- Proficiency control material for quality assurance purposes.
- The alternative assessment is established by the laboratory medical director or designate.
- Proficiency testing or alternate assessment results are monitored by the laboratory medical director or designate at a defined interval and discussed with relevant personnel.
    - Designate reviews all PT results.
    - If non-conforming results that require investigation, will be brought to attention of medical director.
- The laboratory does not communicate with other participants in the inter-laboratory comparison (PT) program about sample data until after the date for submission of the data. The laboratory does not refer inter-laboratory (PT) comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM

Procedure:

1. **Ordering Proficiency Material:**

   Obtain proficiency material from reputable source. Obtained from College of American Pathologists.

QUALITY CROSS CHECK-WHOLE BLOOD GLUCOSE - WBGQ

Analytes/procedures in **bold** type are regulated for proficiency testing by the Centers for Medicare & Medicaid Services (CMS).

Analyte	Challenges/Shipment	Number of Shipments
Glucose	3	Two shipments per year

The CAP Accreditation Program requires all accredited laboratories performing waived whole blood glucose testing using glucose meters to perform alternative performance assessment. This program can be used to meet alternative performance assessment requirements.

Additional Information

Quality Cross Check is a convenient solution to monitor instrument performance and assess comparability across multiple instruments in your laboratory and to identify potential issues before they affect patient results.

How It Works:

Receive three challenges in each of two mailings a year.
Report up to 30 instruments for each challenge.
Receive a custom report package that includes peer group comparison and instrument comparability statistics for each reported analyte.

Program Information

Three 2.0-mL whole blood specimens
Report up to 30 instruments

Shipping Schedule

Shipment A: April
Shipment B: September

Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM

2. **Prepare Proficiency Material:**
    a. Supplies:
        i. Proficiency Material:
            1. 3 vials
            2. Store at room temperature; do not freeze
            3. Viable one month after opening
        ii. Micro-Cuvettes: 3 per glucometer (45 total)
        iii. Micro-Cuvette holder: borrow from cancer genetics
        iv. Micro-Pipettes: 1 per cuvette (45 total)
        v. Biohazard bag: 1 per glucose meter (15 total)
        vi. Labels: 1 per cuvette (see part b.)
        vii. Bi-Yearly Proficiency Report Template: 1 per meter

            Refer to: CAPT_QUA_0700cl1 Bi-Yearly Proficiency Report Template
    b. Label each cuvettes with proficiency test codes ex. 01, 02, 03 etc
    c. In biological safety cabinet:
        i. Wear personal protective equipment
            1. Gown
            2. Gloves
        ii. Perform transfer one PT sample at a time
        iii. Place (15) cuvettes in tube holder
        iv. Add minimum 2 - 3 drops of PT per cuvette
        v. Cap.
        vi. Repeat for PT 2 and PT 3
        vii. Place one of each PT sample cuvette into a biohazard bag with 3 micropipettes. Place template proficiency report in sleeve of biohazard bag.
        viii. Remove personal protective equipment
    d. Delivery proficiency testing to wards/locations.

Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM

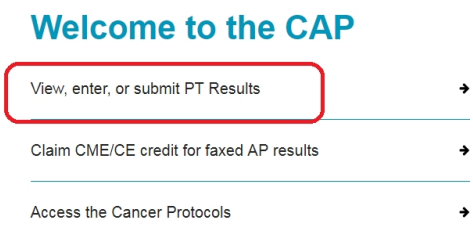
3. **Analyze this specimen as you would a patient's blood sample. Instructions:**

   - Wear gloves
   - Check Meter Name/Serial Number
   - Prepare Nova StatStrip Glucose Meter for Patient Testing. *Perform QC if not already performed within 24hrs.
   - ***Gently mix the sample.*** Tap sample to the bottom of the test tube.
   - Apply sample to the end of the test strip using plastic dropper provided.
   - Record the Glucose Meter results in the area provided on the template.
   - Record test strip code and date & time of testing. Sign initials & operator ID.
   - Dispose of samples in garbage or biohazard container.
   - Send results to:
     1. Directly Labs Site Supervisor (room 3208A)
     2. Scan and email (rgarbuio@bccancer.bc.ca) with attention to Ron Garbuio, POCT PT Results.
     3. Fax. Attn: Ron Garbuio 604 877-6178

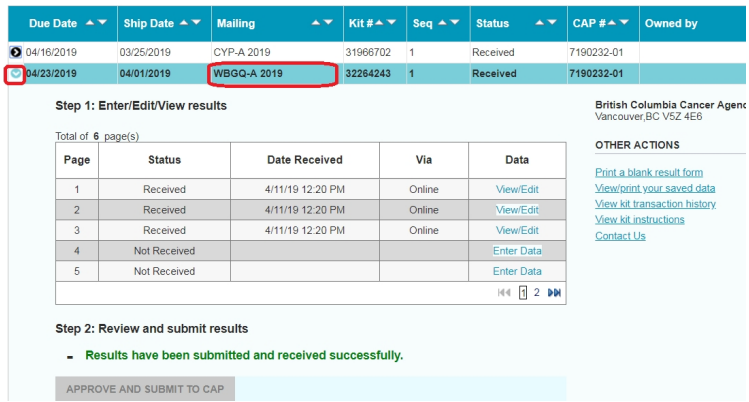
4. **Send the results to CAP online. Do not fax or email. – done by POCT coordinator**

   a. Log into the CAP website

   b. Select View, Enter or submit PT results



   c. Find the proficiency testing in the list



Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM

d. Enter all the results:

   i. Unit of measurement: mmol/L

   ii. Enter the site

   iii. Exceptions – with problem PT

   iv. Results for each PT

   v. Save and submit

e. Save copy in: H:\Lab_Medicine\Pathology Office\Site Supervisor\POCT\Proficiency Testing - CAP\Results

f. Enter results in spreadsheet: H:\Lab_Medicine\Pathology Office\Site Supervisor\POCT\Proficiency Testing – CAP\Results\ Proficiency Testing Results.xlsx

5. POCT PT Assessments

a. Results are monitored by the laboratory medical director or designate within 4 weeks of receiving and discussed with relevant personnel; ex. Point of Care Committee Meetings and Quality Improvement Monthly Meetings.

   Proficiency testing or alternate assessment results are monitored by the laboratory medical director or designate at a defined interval and discussed with relevant personnel.

   i. If all acceptable with no impact to patient care, Site Supervisor/POCT Quality Coordinator can sign the final report

Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM

ii. If non-conforming results, investigated and have signed by Medical Director

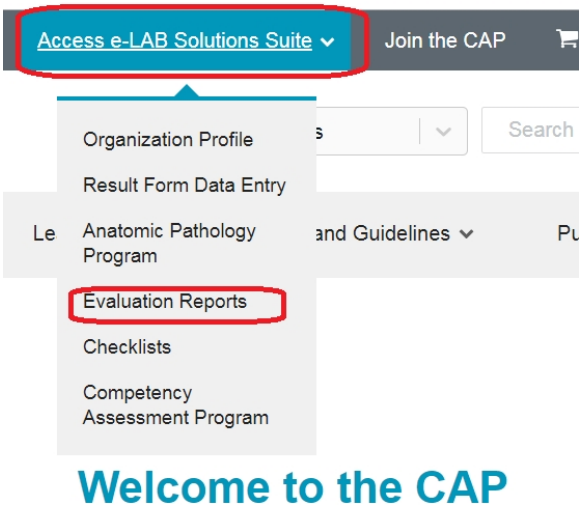
b. Obtain report

i. Go to the CAP website: https://www.cap.org

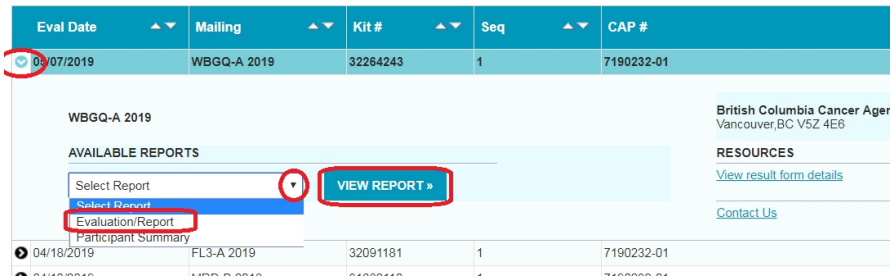
ii. Login

iii. Got to Access e-LAB Solutions Suite

iv. Select Evaluation Reports



v. Select the proficiency test, select the report, and view report



vi. Save a copy of the report in: H:\Lab_Medicine\POCT - Point of Care\Proficiency Testing - CAP\Results

c. Unacceptable POCT PT assessment results are investigated and corrective action is implemented where indicated. This investigation and any corrective action is documented and retained.

i. Laboratory will try to repeat test with same sample on same meter to determine if the error was operator or meter related.

ii. Implement corrective actions

Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM

iii. Check for trends that indicate potential nonconformities

iv. Analyse the root cause – check the PT assessment review/recommendation and consult pathologists

v. Take further action as required to prevent occurrence

vi. File the record of all corrective action

d. The authority to withdraw equipment or discontinue a POCT examination in the event of serious POCT PT or alternate assessment problems is defined.

i. a clinically significant impact to patient results has been confirmed

ii. the accuracy and reliability of test results cannot be verified, or

iii. the cause of significant or ongoing PT exceptions cannot be determined

e. When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff participate in the implementation and recording of corrective actions. The effectiveness of corrective action is monitored.

H:\Lab_Medicine\POCT - Point of Care\! Whole Blood Glucose Meter (Nova & Roche)\Trends\Proficiency Testing

f. Allowable Error:*may vary depending on sample submitted – see final reports

Provided with the result of the evaluations. Example below

Specimen	Evaluation Limit	Allowable Limit
WBGQ-01	± 0.7 %	4.7 – 6.1 mmol/L
WBGQ-02	± 12.5 %	13.2 – 17.1 mmol/L
WBGQ-03	± 12.5 %	17.9 – 23.1 mmol/L

i. Problem glucometers will need to be re-verified before return to ward. Refer to: CAPT_TDE_0300 Validating New/Loaner Glucometer

REFERNCE: https://www.cpsbc.ca/files/pdf/DAP-PT-Manual.pdf

Downloaded by Ronny Garbuio on 2025-03-04 12:55:14 PM