Identifier: Folder:

Subfolder:

| | CAPT_PRG_0400 Pregnancy POCT Proficiency Testing | |
|----------------|--|-----------------|
| CAPT_PRG_0400 | Version #: | 1.2 |
| POCT PREG TEST | Туре: | Procedure (2yr) |
| | Effective on: | 2025-02-24 |

Pregnancy POCT Proficiency Testing CAPT_PRG_0400

Purpose:

The purpose of this document is how to perform proficiency testing on pregnancy test kits.

POCT PT assessment is examined by personnel who routinely examine patient samples.

Proficiency control material for quality assurance purposes.

The alternative assessment is established by the laboratory medical director or designate.

Procedure:

1. Ordering Proficiency Material:

Obtain proficiency material from reputable source. Obtained from Bio-Rad; EQAS Urinalysis Program. Consists of 12 samples, one per month. Stored in fridge between 2-8'C and bring to room temperature before use.

| PT Frequency | | |
|--------------------------------|--------------|-------------------------------------|
| DAP Provisionally Accredited F | acility | |
| DAP reportable measurands | All services | Minimum two samples and one test |
| Non-reportable measurands | All services | event prior to full DAP assessment |
| DAP Accredited Facility | | |
| DAP reportable measurands | All services | Minimum four samples per year |
| Non-reportable measurands | All services | Minimum two testing events per year |

2. Prepare Proficiency Material:

- a. Supplies:
 - i. Proficiency Material:
 - 1. 1 vial per month.
 - Store at refrigerator (2 8'C) until ready to use. Do not freeze. Test at room temperature.
 - ii. Reporting Document. Refer to:
 - CAPT_PRG_0400F1 Proficiency Testing One Step hCG Pregnancy Test
- b. In Biological Safety Cabinet (BSC):
 - i. Wearing gloves and gown. Transfer

| Written by: | Ronny Garbuio | Approved by (sign.): | | |
|--------------|---------------|--|------------|--|
| Reviewed by: | | | | |
| Reviewed on: | | Approved by (name): | Gang Wang | |
| Renewed by: | Ronny Garbuio | Approved on: | 2025-01-28 | |
| Renewed on: | 2025-02-24 | Revision Date: | 2027-02-24 | |
| | | Documents used outside of OMNI are uncontrolled. | | |
| | | | | |

- Using a 15mL test tube, found in Cancer Genetics, transfer 1/3 the solution to a labelled tube. This is to be used by lab to run test concurrently with test site. This will be used to do test the urine dipsticks and pregnancy tests.
- 2/3 still in original tube, will be used at location doing the proficiency testing. Note: 1ml will be transferred to micro-cuvette for pregnancy PT.

| SAMPLE | LOCATION | LOT | DELIVER TO LOCATION | |
|--------|----------------|--------|---------------------|------------|
| 1 | | 360801 | 2024-04-11 | 2024-04-17 |
| 2 | | 360802 | 2024-04-17 | 2024-04-24 |
| 3 | 2nd Floor | 360803 | 2024-05-02 | 2024-05-08 |
| 4 | 1 | 360804 | 2024-06-06 | 2024-06-12 |
| 5 | Surgical Suite | 360805 | 2024-07-04 | 2024-07-10 |
| 6 | Ŭ | 360806 | 2024-08-08 | 2024-08-14 |
| 7 | | 360807 | 2024-09-05 | 2024-09-11 |
| 8 | | 360808 | 2024-10-02 | 2024-10-09 |
| 9 | | 360809 | 2024-11-06 | 2024-11-13 |
| 10 | | 360810 | 2024-12-05 | 2024-12-11 |
| 11 | | 360811 | 2025-01-02 | 2025-01-08 |
| 12 | 1 | 360812 | 2025-02-06 | 2025-02-12 |

c. Delivery proficiency testing to the ward/location -2^{nd} floor surgical suite.

Example of Pregnancy PT schedule

- 3. Analyze the test sample as you would a patient's urine sample.
 - a. Refer to: CAPT_PRG_0100 Pregnancy Test Procedure
 - b. Apply 3 full drops to well.
 - c. Wait 5 minutes to maximum of 10 minutes. Do not read results after 10 minutes.
- 4. Record the results on document:
 - a. CAPT_PRG_0400F1 Proficiency Testing One Step hCG Pregnancy Test
- 5. Dispose of sample in accordance to department biohazard container.
- 6. Send results to Labs Site Supervisor (room 3028A) fax (604 877-6178) or scan and email (<u>rgarbuio@bccancer.bc.ca</u>) with attention to Ron Garbuio, POCT PT Results.
- 7. The lab will run concurrent results should as a backup for troubleshooting purposes should test location result not conform to result.
- 8. Submitting Results* Done by POCT coordinator

*submit few days before due date do to time zone differences.

- a. Log into Bio-Rad: qcnet https://www.qcnet.com/
- b. Select EQAS EQAS Online & Reports

| QCNet | Quality Controls | QC Data Manageme | nt Resources | Support | Q | My account Sign (| Dut BIO RAD |
|--------------|------------------|------------------|--------------|---------------------------|------------|---------------------|------------------|
| | | | | | | Peer reports M | ly einserts EQAS |
| | | | | | | 1 1 | - |
| | | | | | | | |
| QC Data Mana | gement Res | ources Supp | ort | Q | My account | Sign Out 🛛 🖪 | NO RAD |
| | | | | EQA | S Online | EQAS EQAS lendar | bulletin |
| | | | | $\langle \langle \rangle$ | | | |

c. Select Lab ID:

Select Lab ID: 191546 (Note 190405 is for urine dipsticks)

| EQAS Online | BIO RAD |
|--|---|
| Home Configure Data Entry Reports Log Out | Logged in as: <u>rgarbuio@bccancer</u> Monday, January 27, 2025 6:04 PM |
| Lab ID: 191546 BC CANCER AGENCY | |
| Urinalysis Program - Cycle 9 | <u>Messages(0)</u> |
| 1 2 3 4 5 6 7 17 Apr 24 Apr 8 May 12 Jun 10 Jul 14 Aug 11 Se | 8 9 10 11 12 9 Oct 13 Nov 11 Dec 8 Jan 12 Feb |
| 🔲 All Results Saved 🗌 Missing Results 📕 Active Sample & Missing Results 📋 Late R | esults * Amended Results |

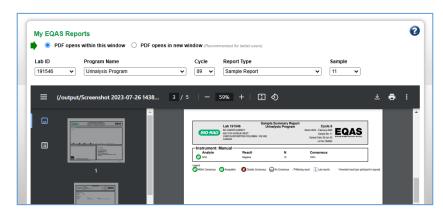
- d. Select the cycle that is due (in orange)
- e. Enter the results provided by the nursing staff into the appropriate fields.
 - i. Negative
 - ii. Positive
 - iii. Invalid

| ab ID: * 191546 BC CANCER AGENCY | | Program Name Urinalysis Prog | | | | |
|---|--|----------------------------------|-----------|----------------------------|--------------------|---------------------|
| | | Uninalysis Prog | ram - Cyc | 716.9 | ~ | \frown |
| 1 2 3 17 Apr 24 Apr 8 May | 4 5 6 12 Jun 10 Jul 14 Aug | 7 8 11 Sep 9 Oct | 9 13 N | | 11 8 Jan | 12 12 Feb |
| All Results Saved 🔲 Missing Results | Active Sample & Missing Results | 1 Late Results * An | nended Re | sults | | |
| All Results Saved Missing Results Analyte CG. | Active Sample & Missing Results Result | 1 Late Results * An | UR | sults Submission date & | time (User) | |

- f. Select Save
- 9. Review reports. * will be notified via email when complete.
 - a. On EQAS online select EQAS Online & Reports
 - b. Select Reports My EQAS Reports

| EQAS Online | | | | | |
|-----------------------------------|----------------------------------|------------------------------|--|--|--|
| Home Configure Data Entry | Reports Log O My EQAS Reports | | | | |
| Data Entry | View Audit Trail | | | | |
| Lab ID: * 191546 BC CANCER AGENCY | ~ | Program Name: * | | | |
| | | Urinalysis Program - Cycle 9 | | | |

c. Select the Lab, Program Name, Cycle and Report type (Sample Report)



- d. Save reports in folder: H:\Lab_Medicine\POCT Point of Care\!! Pregnancy Test (Technologist Choice)\Proficiency Testing\Results
- e. Review the results

10. POCT PT Assessments

a. Results are monitored by the laboratory medical director/POCT Quality Coordinator reviewed within 4 weeks of receiving and discussed with relevant personnel; Point of Care Committee Meetings and Quality Improvement Monthly Meeting.

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
- ii. If non-conforming results, investigated and have signed by Medical Director
- b. Unacceptable POCT PT assessment results are investigated and corrective action is implemented where indicated. This investigation and any corrective action is documented and retained.
 - Implement corrective actions
 - Check for trends that indicate potential nonconformities
 - Analyse the root cause check the PT assessment review/recommendation and consult medical director
 - Take further action as required to prevent occurrence
 - File the record of all corrective action
 - YOU DO NOT NEED TO SUBMIT TO DAP
 - While all PT exceptions need to be investigated, not all need to be reported to the DAP. Urinalysis is one that does not need to be reported to the DAP.
 - For more information about <u>Reportable Measurands</u> refer to the DAP website.
- c. The authority to withdraw/discontinue a POCT examination in the event of serious POCT PT 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
- d. 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.