Procedure

Procedure Title:	Abaxis Piccolo® Operating Procedure – Point of Care Testing (POCT)	
Applies To:	Health Care Professionals performing POCT using the Abaxis Piccolo®	
Governing Policy:	Point of Care Testing Operations - DT-POC-001	
Approved:	**Effective:**	**Next Review:**
July 13, 2023	August 8, 2023	July 13, 2027
Sponsor:	Senior Medical Director, Diagnostic and Therapeutic Services Senior Director, Clinical Networks	
Approval Authority:	Senior Medical Director, Diagnostic and Therapeutic Services Senior Director, Clinical Networks	
Number: DT-POC-005	**Manual:** Diagnostic Testing	

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PURPOSE

This procedure provides information and instruction required to operate the Abaxis Piccolo® device.

GUIDELINES

1. The Piccolo® is intended for use in situations when results are needed immediately.
2. Consider all patient specimens, as well as the materials they contact, as biohazardous and capable of transmitting infection or cross contamination.
3. Follow consistent inventory management practices, such as proper storage and labelling of supplies, and inventory rotation to support quality POCT results, and patient safety.
4. Follow local processes to determine responsibility to complete aspects of this procedure.

COMPETENCY REQUIREMENTS

1. The Health Care Professional is responsible to demonstrate competency in the use of the Piccolo® prior to performing patient testing, or any part of this procedure, as per POCT Training and Competency Assessment - DT-POC-002.

> **Note:** The HCP may not be trained to all parts of this procedure and should not perform any part to which they have not been trained.

PROCEDURE

Equipment and Supplies Handling

1. Follow Table 1 for maintaining stability and storage of reagents/supplies.

Table 1: Stability, Storage and Handling Instructions for Piccolo® Liver Panel Plus Discs

Stability and Storage	Handling
Unopened: ○ Store at 2 to 8 degrees Celsius (ºC) until the manufacturer expiry date. ○ Stable at 15 to 30ºC for 48 hours. ○ When storing at 15 to 30ºC, label with initials and new expiry date and time. **Opened:** ○ Stable at 15 to 30ºC for 20 minutes. ○ **Do not** return a disc to the refrigerator once it has been at room temperature, or after pouch has been opened.	○ Discs are fragile. Always handle with care. ○ Use powder-free gloves to handle discs. ○ Touch discs only along their edges and hold in a flat position. ○ Do not use a disk that has been dropped or appears damaged.

2. Follow Table 2 for Liquid Quality Control (QC) practices.

Table 2: Liquid Quality Control for the Piccolo®

Control	Levels	Stability and storage	Frequency	Preparation
Bio-Rad Liquid Assayed Multiqual®	1 and 3	**Unopened:** ○ Store at -20 to -70ºC until manufacturer expiry date. **Opened:** ○ Store at 2 to 8ºC for nine days. ○ After opening, record the open expiry date on the vial.	○ Monthly ○ After switching to a new lot number of reagent or after receiving new reagents.	1. Thaw at room temperature for one hour or until completely thawed. 2. Gently swirl content until there are no visible signs of precipitate.

3. Perform maintenance tasks as outlined in Appendix B and document completed tasks on maintenance checklist.
4. Gather the following materials and equipment prior to testing, as required:
   - Liver Panel Plus discs
   - Liquid QC level 1 and 3
   - Pipette
   - Pipette tips
   - Dispensing tips
   - Protective gloves

- Piccolo®
- Thermal paper

Quality Control Testing (as per frequency in Table 2.)

> **Note:** It is recommended to perform any required maintenance procedures, prior to performing QC.

1. Ensure discs and QC are not expired. Discard any outdated supplies. See Table 1 and Table 2.
2. Prepare QC as per Table 2. Don clean gloves.
3. Turn the device on.
4. Remove reagent disc from refrigerator and confirm the expiry date. Remove wrapping.
5. Fill the sample chamber on the disc with QC solution using a pipette.

> **Note:**
> - Begin testing immediately (within **10 minutes**) after dispensing QC solution into the reagent disc.
> - Remove any QC solution spilled on the outside of the disc.
> - Do not overfill the sample chamber.
> - Do not withdraw any QC solution from the sample port.

6. Press **Analyze**.
7. Place the disc in recessed area in the drawer. Press **Close**.

> **Note:** Analysis takes approximately 12 minutes.

8. Scan or manually enter operator ID and press Done.
9. Select the correct Control.
10. Manually enter QC lot number. Press Done.
11. When analysis is complete, press Open.
12. Remove the disc and discard in a biohazard waste container. Press Close.
13. Repeat this process for second QC solution.
14. Interpret Liquid QC Results.
    - **PASS** must be obtained for both Levels 1 and 3 to proceed with patient testing.
    - If a **FAIL** result is obtained, do not perform patient testing. Repeat the control that failed. Refer to Appendix C.
    - If an error occurs, analysis will be cancelled. Repeat the test.
15. Turn device off.

Patient Testing

Note: Patient testing requires a written or verbal order from an Authorized Prescriber, or an approved care directive.

1. Ensure all required maintenance and QC procedures are complete before performing patient testing.
2. Verify there is a written or verbal order from an Authorized Prescriber, or as per direction in an approved care directive.
3. Identify patient, as per Patient Identification - NSHA CL-SR-025.
4. Collect and properly label a dark green lithium heparin vacutainer tube, as per Venipuncture for Blood Specimen Collection - NSHA CL-BP-040.
5. Document the date and time the specimen was collected as per local work instructions.
6. Ensure the specimen is suitable for testing. See Appendix D.
7. Perform hand hygiene and don clean gloves.
8. Turn device on.
9. Remove reagent disc from refrigerator and confirm the expiry date. Remove wrapping.
10. Insert tube into dispensing tip. Do not uncap tube. Tilt tube and dispensing tip at 45˚ angle to disc.
11. Push down on bottom of tube with a slow, continuous motion, dispensing blood into the sample chamber until filled to the sample fill line, indicated by two arrows on the disc.

Note:

- Begin testing immediately (within **10 minutes**) after dispensing patient specimen into the reagent disc.
- Remove any blood spilled on the outside of the disc.
- Do not overfill the sample chamber.
- Do not withdraw any blood from the sample port.

12. Discard the dispensing tip into biohazard sharps container.
13. Press Analyze.

Note: Analysis takes approximately 12 minutes.

14. Place the disc in recessed area in the drawer. Press Close.
15. Scan or manually enter operator ID. Press Done.
16. Select Patient.
17. Scan or manually enter the patient's account number from the vacutainer tube. Press Done.

Note: If an error occurs, analysis will be cancelled. Repeat testing, and document in patient chart.

18. When analysis is complete, press **Open**.
19. Remove the disc and discard in a biohazard waste container. Press **Close**.
20. Interpret Results.
    20.1. Check results for the following flags or errors:
        - An asterisk (*) identifies results outside reference range.
        - A "less than (<)" or a "greater than (>)" symbol identifies values outside analytical range. Referring specimen to the laboratory for further testing is recommended.
        - A "~~~" printed in place of numbers identifies result is unavailable or suppressed. Repeat testing is recommended.
        - If a result is suppressed and HEM is indicated, the specimen is hemolyzed and has adversely affected the results. Collect a new specimen and repeat testing.
        - If a result is suppressed and ICT or LIP is indicated, the specimen is icteric or lipemic and has adversely affected the results. Collect a new specimen and send it to the laboratory for testing.

    20.2. Refer to Appendix E for reference ranges and analytical ranges.

Note:

- If the patient's symptoms are inconsistent with results, refer to Appendix C.
- Sample indices are included at the bottom of the results printout. These indices indicate degree of hemolysis, icterus, and lipemia found in the specimen.
- The message "QC OK" is printed with results when monitored test conditions are within the expected ranges. If they are outside the expected range, the analysis is cancelled. Refer to Appendix C.
- Refer to Abaxis Piccolo® Operator's Manual and Liver Panel Plus Instructions for Use for principles of testing, performance characteristics, limitations of testing and list of interfering substances.

21. Results will print and automatically transfer to the patient's electronic record. During downtime, or if results do not appear in electronic records:
    21.1. Label a Point of Care Testing Results Form with at least two person-specific patient identifiers and attach the result printout from the Piccolo® to the result form.
    21.2. Make a photocopy of the result form and place the photocopied result form in the patient's chart.

Note: Thermal printer paper will fade over time. The result form must be photocopied to create a permanent record.

22. Turn device off.
23. Retain specimen as per local work instructions and clean work area.
24. Remove gloves and perform hand hygiene.

REFERENCES

Abaxis Piccolo® Operator's Manual, 2020.

Liver Panel Plus Package Insert, January 2016.

Bio-Rad Liquid Assayed Multiqual® Instructions for Use, February 2022.

Accreditation Canada. (2019). *Qmentum program standards. Point of care testing*. Ver. 14.

RELATED DOCUMENTS

Policies

POCT Operations - NSHA DT-POC-001

POCT Training and Competence - NSHA DT-POC-002

Venipuncture for Blood Specimen Collection - NSHA CL-BP-040

Patient Identification - NSHA CL-SR-025

Hand Hygiene – NSHA IPC-RP-020

Routine Practices – NSHA IPC-RP-005

Waste Management – NSHA ENV-WS-001

Sharps Safety – NSHA AD-OHS-005

Forms

Point of Care Testing Results Form

Appendices

Appendix A: Definitions

Appendix B: Maintenance

Appendix C: Troubleshooting

Appendix D: Specimen Requirement and Rejection Criteria

Appendix E: Reference Ranges and Analytical Ranges

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Appendix A: Definitions

Authorized Prescriber	A Regulated Health Care Professional who is permitted by legislation, their regulatory college, Nova Scotia Health/IWK Health, and practice setting (where applicable) to prescribe medications/treatments and order diagnostic tests within their scope of practice or employment. To have the authority to prescribe in Nova Scotia, the authorized prescriber must be a Regulated Health Care Professional, registered (in good standing), and practicing within the Nova Scotia Health/IWK Health/First Nations Health Service Delivery structure and has a Contractual Arrangement with, hold privileges with, or employed by Nova Scotia Health/IWK Health to provide health care services to Nova Scotians. Prescribers external to and have no contractual arrangement with Nova Scotia Health/IWK Health/First Nations Community Health Centre may not prescribe within Nova Scotia Health practice settings.
Health Care Professional (HCP) performing Point-of-Care Testing	A professional recognized as qualified by the appropriate professional college or association and pursuant to the professional legislation in force, following appropriate training, to perform the duties of collecting samples and determining the result of POCT as well as counselling the client if necessary. This healthcare professional may be a Physician, Nurse Practitioner, Medical Laboratory Technologist, Registered Nurse, Licensed Practical Nurse, Pharmacist, Paramedic, Respiratory Therapist or Medical Radiation Technologist provided they are members of their professional associations and have received appropriate training.
Point-of-Care testing (POCT)	Testing that is performed near or at the site of the patient with the result leading to possible change in the care of the patient.
Quality Control (QC)	The set of procedures designed to monitor the test method and the results to assure test system performance by detecting gradual or sudden changes in performance.

Appendix B: Maintenance

Daily

1. Check that paper supply is adequate. If not, replace paper.
2. To replace paper:
   2.1. Open the printer cover
   2.2. Put new roll into the printer so that the paper unrolls from the bottom of the roll and out towards the front of the analyzer.
   2.3. Ensure paper extends out of the printer slot
   2.4. Press the cover closed until it locks into place.
   2.5. Pull gently on the end of the paper until it is tight.

Monthly (or as needed)

1. Clean the display screen using a 10% bleach solution. Apply solution to a lint free cloth and wipe the screen.
2. Clean the analyzer with a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution, such as, a 10% bleach solution, or a 30% isopropyl alcohol solution. Pre-soaked towelettes (isopropyl alcohol) may be used as an alternate.

Note:

- Do not use any cleaner containing alcohol on display screen.
- Do not spray cleaner directly onto the display. Dampen a cloth instead.

Bi-Annual (or as needed)

1. Clean air filter.
   1.1. Unplug the device and remove power cord from back of the analyzer.
   1.2. Grasp black mesh filter in circular opening and remove it.
   1.3. Wash the filter in warm soapy water and dry completely.
   1.4. Place the clean, dry filter flat in the circular opening and push sides of the filter behind the edges of the circular opening.
   1.5. Plug power cord into back of device.

Appendix C: Troubleshooting

Patient Testing Troubleshooting
1. If questioning the validity of the result: • Ensure discs used were stored in proper conditions and are not expired. • Repeat testing with a new disc. • Repeat testing with a new specimen. • Refer to Liver Panel Plus Instructions for Use for list of interfering substances. • Follow up with laboratory testing. 2. Document actions in the patient chart.
Liquid Quality Control Testing Troubleshooting
1. If a "FAIL" result is obtained: • Ensure QC and discs were stored in proper conditions and are not expired. Repeat testing. • Repeat testing using a previously unopen vial of QC. 2. If a "PASS" result is not obtained: • **Do not** perform patient testing. • Contact POCT Specialist.
When to Contact POCT Specialist
1. Contact POCT Specialist if: • Patient's symptoms are inconsistent with results from device and troubleshooting has been performed. • Testing was performed which led to results on a wrong patient record. • A "PASS" result cannot be obtained during QC testing and troubleshooting has been performed. • Unable to resolve problems or error messages after troubleshooting. • The device will not turn on. • There is any physical damage to the device.

Appendix D: Specimen Requirement and Rejection Criteria

Specimen Requirements

- Whole blood collected in a dark green lithium heparin vacutainer tube.
- Tube must be full.
- Specimen was collected within the last 60 minutes.

Note:

- Total bilirubin results may be adversely affected by exposure to light.
- Whole blood specimens not run immediately should be stored in the dark for no longer than 60 minutes.

Specimen Rejection

1. Reject the specimen if:
   - The specimen is not labelled with two Patient Specific Patient Identifiers.
   - There is evidence of clotting.
   - The specimen was collected in a vacutainer tube other than a dark green lithium heparin.
   - Incompletely filled.
   - The specimen is older than 60 minutes.

Appendix E: Reference Ranges and Analytical Ranges

Analyte	Reference Range	Analytical Range	Units
Albumin (ALB)	33 – 55	10 – 65	g/L
Alkaline Phosphatase (ALP)	42 – 141 (females) 53 – 128 (males) 42 - 141 (unidentified)	5 – 2400	U/L
Alanine Aminotransferase (ALT)	10 – 47	5 – 2000	U/L
Amylase (AMY)	14 – 97	5 – 4000	U/L
Aspartate Aminotransferase (AST)	11 – 38	5 – 2000	U/L
Total Bilirubin (TBIL)	3 – 27	1.7 – 513	µmol/L
Gamma Glutamyltransferase (GGT)	5 – 65	5 – 3000	U/L
Total Protein (TP)	64 – 81	20 – 140	g/L

VERSION HISTORY

Version:	Effective:	Approved by:	What's changed:
Original	2018-05-31	VP Integrated Health Services Program of Care 2 and Chief Nursing Officer	N/A
Standard Review	2023-08-08	Senior Medical Director, Diagnostic and Therapeutic Services Senior Director, Clinical Networks	○ Updated QC product names, definitions ○ Revised Appendix for troubleshooting ○ Simplified test procedure instructions