UI Health | UIC

Surgery O.R. Laboratory

Direct Observation Competency Assessment

Instrumentation Laboratory – GEM Premier 5000

_____Initial Training for New Operator _____6 Month Assessment (required for new operators)

_____12 month (Annual) Assessment

Operator Name (print) _____

POCT TEST (patient test or previously analyzed sample) **At least one direct observation must be documented in each row for each test type that applies**	**Blood Gas** Record date / name of **observer** in appropriate box below
Direct Observation of Patient Identification, Collection of sample, testing, and reporting of patient results: 1. Knows the sample requirements: container type, storage and stability. 2. Runs patient samples and reviews results according to policy. 3. Verifies patient results in LIS. 4. Verifies patient sample identification before analysis. 5. Follows the Laboratory policy for mislabeled/unlabeled .	
Direct Observation of performance of Quality control (Liquid or Electronic): 1. Understands QC rules and documents corrective action according to policy. 2. Performs Gem System Evaluator - L2 after the change of each GEM 5000 sample cartridge.	
Direct Observation of performance of instrument maintenance: 1. Disinfect instrument as necessary. 2. Retain iQM2 reports (Corrective action, Delta Check, and CVP reports).	
Monitoring, recording, and reporting of test results: 1. Understands calibration results, drift, status and sensitivity. 2. Understands and is able to run Performance Verification Process. 3. Knows linear ranges and reference ranges of analytes.	
Review of intermediate patient test results, quality control, and Proficiency Tests (PT): 1. Review iQM2 reports. 2. Reviews patient results according to policy. 3. Reviews PT according to policy.	

UI Health | UIC

Surgery O.R. Laboratory

Test performance as defined by lab policy (e.g. testing previously analyzed specimens, internal blind testing samples, external proficiency on testing samples). 1. Is able to load the GEM 5000 Pak sample cartridge. 2. Performs inventory as needed. 3. Has knowledge when to initiate Auto PAK Validation. 4. Has knowledge of PT and instrument comparison. 5. Has read and is knowledgeable about contents of the policy and procedure.	

By documenting your name as the observer, you are verifying that the associate followed policy and procedure appropriately.

OBSERVED BY (please print full legal name) _____ **TITLE:** _____

OBSERVER'S SIGNATURE: _____ **DATE:** _____

EMPLOYEE'S SIGNATURE: _____ **DATE:** _____

UI Health | UIC

Surgery O.R. Laboratory

IL GEM Premier 5000-Quiz

Operator Name/ Title: _____ **Location:** _____ **UIN:** _____

Circle the correct answer.

1. The GEM Premier 5000 key components are:
    a. Analyzer
    b. Cartridge
    c. Ampoule breaker
    d. Both a and b
2. The GEM Premier 5000 cartridge must be:
    a. Stored at room temperature 15 to 25°C (59 to 77°F)
    b. Refrigerated
    c. Frozen
3. The typical length of cartridge warms up and auto Pak validation can be up to:
    a. 10 minutes
    b. 40 minutes
    c. 90 minutes
    d. 100 minutes
4. The types of sampling devices accepted for the GEM Premier 5000 are:
    a. Syringe
    b. Capillary tube
    c. Ampoules
    d. All of the above
5. Samples do not need to be mixed prior to analysis on the GEM Premier 5000
    a. True
    b. False
6. Source(s) of error associated with poor sample handling include:
    a. Air or clots in syringe
    b. Syringe not heparinized
    c. Inadequate sample mixing
    d. All of the above
7. If an analyte is grayed out, the operator can initiate a background check to correct errors by selecting: diagnostic and run iQM2 process.
    a. True
    b. False

Surgery O.R. Laboratory

8. Once the analyzer is shut down the operator will need to replace the cartridge, if power is not restored within how many minutes?
    a. 60 minutes
    b. 30 minutes
    c. 25 minutes
    d. 45 minutes
9. Sampling can be initiated from either the "Quick Start", "Manual Selection" or "Ampoule" tabs.
    a. True
    b. False
10. After the GEM 5000 sample cartridge is replaced, GEM System Evaluator (Level 2) must be performed before patient testing.
    a. True
    b. False
11. The GEM PAK should be stored in foil pack prior to use and it can be used until the expiration date indicated on the label of each GEM PAK.
    a. True
    b. False
12. Patient results can be reported when the analyte has an absorbance error.
    a. True
    b. False

Operator Signature: _____ Date: _____

Trainer Signature: _____ Date: _____