Next week on June 26 we will begin running Procalcitonin on the AR3 – I side

**Clinical Significance**

* Aid in the risk assessment of critically ill patients on their first day of intensive care unit (ICU) admission for progression to severe sepsis and septic shock.
* Aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time.
* Aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) – defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department.
* Aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

**Methodology**

The ARCHITECT B∙R∙A∙H∙M∙S PCT assay is a two-step immunoassay for the quantitative determination of PCT in plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

Specimen Collection

|  |  |
| --- | --- |
| Plasma | Lithium Heparin PST |

Unacceptable specimens

* Do not use specimens with the following conditions:
* heat-inactivated
* pooled
* grossly hemolyzed
* obvious microbial contamination
* fungal growth

Storage

| Specimen Type | Storage Temperature | Maximum Storage Time |
| --- | --- | --- |
| Plasma | Room temperature | ≤ 8 hours on the clot, red blood cells, or separator gel |
| ≤ 24 hours off the clot, red blood cells, or separator gel |
| 2-8°C | ≤ 48 hours off the clot, red blood cells, or separator gel |
| -10°C or colder | ≤ 15 days off the clot, red blood cells, or separator gel |

If stored beyond 8 hours, remove serum or plasma from the clot, red blood cells, or separator gel and store at 2-8°C or -10°C or colder

## Reagent Storage

* Do not freeze.

When stored and handled as directed, reagents are stable until the expiration date.

|  | Storage Temperature | Maximum Storage Time | Additional Storage Instructions |
| --- | --- | --- | --- |
| **Unopened/Opened** | 2-8°C | Until expiration date | May be used immediately after removal from 2-8°C storage.  Store in upright position. |
| **On board**\* | System temperature | 25 days | Discard after 25 days.  For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5. |

**Calibrators**

**Storage**

Calibrators must be stored frozen at -10 C or colder when not in use.

Do not uses past expiration date

Calibrators are stable until the expiration date when stored and handled as directed.

**Preparation for Analysis**

Thaw calibrators are room temperature (15 – 30 C until completely thawed (30 – 60 minutes)

Mix by gentle inversion at least 10 times prior to use

After each use, tightly close the caps and return to -10 c or colder for storage.

Record each thaw date on the box to track the number of times the calibrators are thawed.

Avoid more than 3 freeze/thaw cycles.

* Test Calibrators A-F in duplicate. 8 drops are needed for the calibration. The calibrators should be priority loaded.

A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.

* Calibration Range: 0.00 - 100.00 ng/mL (0.00 - 100.00 µg/L).

**Controls**

3 levels of Abbott Architect B.R.A.H.M.S Controls are run every 12 hours in which patients are run.

**Storage**

Controls must be stored frozen at -10 C or colder. After thaw, store at 2-8 C for up to 30 days.

Do not use past expiration date

**Preparation for Analysis**

Thaw controls at room temperature (15-30 C) until completely thawed (30 – 60 minutes).

Mix by gentle inversion (10 times) prior to each use. The 30 day expiration date must be written on the box after thawing

6 drops are needed for the controls.

Record Procalcitonin QC in Unity under AR3, Procalcitonin Control

**Linearity**

The measuring interval of the ARCHITECT B∙R∙A∙H∙M∙S PCT assay is 0.02 to 100.00 ng/mL. When using the 1:10 automated dilution protocol, the assay can report values up to 1000.00 ng/mL

**Automated Dilution Protocol**

The system performs a 1:10 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result

**Reference Range:**

Reference range 0.15 ng/mL

**Interpretation of Results**

1. **Risk assessment for progression to severe sepsis and septic shock**

The ARCHITECT B∙R∙A∙H∙M∙S PCT assay is intended to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.

Systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis, and septic shock were categorized according to the criteria of the consensus conference of the American College of Chest Physicians / Society of Critical Care Medicine.[*22*](#unique_5_Connect_42_li_tps_v2g_lx)

PCT should always be interpreted in the clinical context of the patient. Therefore, clinicians should use the PCT results in conjunction with other laboratory findings and clinical signs of the patient.

Data support the following interpretative risk assessment criteria:*[9](#unique_5_Connect_42_li_yff_lzf_lx),* [*10*](#unique_5_Connect_42_li_jnt_lzf_lx)*,* [*23*](#unique_5_Connect_42_li_smm_m1x_vy)

* **PCT > 2.0 ng/mL:** A PCT level above 2.0 ng/mL on the first day of ICU admission is associated with a high risk for progression to severe sepsis and/or septic shock.
* **PCT < 0.5 ng/mL:** A PCT level below 0.5 ng/mL on the first day of ICU admission is associated with a low risk for progression to severe sepsis and/or septic shock.

Note: PCT levels below 0.5 ng/mL do not exclude an infection, because localized infections (without systemic signs) may also be associated with such low levels. If the PCT measurement is done very early after the systemic infection process has started (usually < 6 hours), these values may still be low.

Various non-infectious conditions are known to induce changes in PCT level. PCT levels between 0.5 ng/mL and 2.0 ng/mL should be interpreted in the context of the specific clinical background and condition(s) of the individual patient. It is recommended to retest PCT within 6–24 hours if any concentrations < 2.0 ng/mL are obtained.

Refer to the Procalcitonin procedure or package insert for further discussion of interpretation of results.