



## **CHEM.ARCH.ASSAY.100.0 Sekisui Diagnostics Acetaminophen Assay for Architect**

### **STATEMENT OF PURPOSE**

The Sekisui Acetaminophen assay uses enzymatic/colorimetric methodology for the quantitative determination of acetaminophen in human serum or plasma.

### **OWNERS**

Manager, Regional Chemistry

### **RELATED DOCUMENTS**

CHEM.ARCH.1.0 Architect System Overview

CHEM.ARCH.5.0 Architect ci System Assay Calibration

CHEM.ARCH.6.0

### **SPECIMEN**

#### A. Specimen requirements

1. Serum (Red top)
2. Plasma (lithium heparin)

#### B. Specimen stability

1. Refrigerated (4-8°C) 14 days
2. Frozen (<-20°C) 45 days

#### C. Minimum volume 64 µL

#### D. Special Instructions

1. Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

### **MATERIALS**

1. Sekisui Reagent and Calibrator kit.
2. Controls
3. DI H<sub>2</sub>O
4. 0.9% Saline



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### REAGENTS

Sekisui Acetaminophen Reagent Kit is supplied as a liquid, ready-to-use, two-reagent kit which contains R1 and R2. Refer to Package Insert for chemical composition.

1. Before use, invert several times, avoiding the formation of bubbles. Assure reagents are clear before use.
2. Pour Sekisui Reagent R1 and R2 into 2 different Abbott User Defined Reagent Cartridges and label appropriately. (When either the R1 or the R2 reagent cartridge becomes empty, replace both cartridges.)
3. Unopened reagents are stable until the expiration date when stored at 2 to 8°C.
4. Supplied reagents are stable at 2-8 degrees C for 28 days.
5. Remove air bubbles, if present in the reagent cartridge, with an applicator stick.
6. Do not use components beyond the expiration date.
7. Do not mix materials from different kit lot numbers.

### EQUIPMENT

ARCHITECT *c* System

### CALIBRATION

An acetaminophen calibrator is included in the kit. Assay calibration is good for 4 days.

See CHEM.ARCH.5.0 *Architect ci System Assay Calibration*

### QUALITY CONTROL

A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedures, CHEM.ARCH.6.0 and HBL.GEN.7.0 for specific details.

### PROCEDURE

1. See Architect operating procedures for a detailed description of how to operate the applicable Architect instrument.
2. Loading non-bar coded reagents:
  - a) Select **F6- Assign Location** on the Reagent Status Screen.
  - b) Select the desired reagent from the Reagent kits table.
  - c) Select the desired Reagent Supply Center option, and then the desired location in the data entry box.
  - d) Select **Add** - the assigned position displays in the reagent kits table.
  - e) Verify the expiration date of the reagent.
  - f) Invert the reagent cartridge gently to ensure a homogenous solution.
  - g) Remove and discard the cap.
  - h) Remove air bubbles, if needed, with a clean applicator stick.



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- i) Open the Reagent Supply Center cover.
- j) Place the reagent cartridge in the assigned location on the Reagent Supply Center.
- k) Close Reagent Supply Center cover.
- l) Select **Done** on the Assign location window to return to the Reagent status screen.

### DILUTIONS

- A. Specimens with Acetaminophen values exceeding 378 µg/mL shall be manually diluted with 0.9% saline.
- B. Specimens with Acetaminophen values exceeding 3780 µg/mL shall be reported as > 3780 µg/mL.
- C. If physician requests further dilution, dilution to end point, by perform a manual dilution using 0.85%-0.9% Saline. Document "Physician requested dilution to endpoint." (PRDIL)

### REPORTING RESULTS

- A. Normal Range: 10 – 30 µg/mL
- B. Critical Value: > 150 µg/mL
- C. Linear Range: 3 – 378 µg/mL

### Result Entry

- A. Sunquest Computer Entry
  1. Manual Entry
    - Function: MEM
    - Worksheet: Worksheet specific to site
    - Test Code: ACETO
  2. Online Entry
    - Function: OEM
    - Device: Device method specific to site
    - Test Code: ACETO
- B. QLS Computer Entry
  1. Enter: 3, 3, 1
  2. Worksheet: Enter worksheet from QLS label.
  3. Accession number: Scan bar code or enter JI number.

**NOTE:** If HIS or LIS system is down, see appropriate Laboratory Computer Downtime Policy.

### LIMITATIONS

1. Hemoglobin showed a positive bias; therefore hemolyzed samples should not be used.
2. All acetaminophens with results  $\geq 200$  µg/mL will result with the message "For patients receiving N-acetylcysteine (NAC) therapy, concentrations above 200 mg/L may falsely depress



Sekisui Diagnostics Acetaminophen Assay for Architect acetaminophen results. Interpret significance of test results based upon patient’s clinical information”.

## REFERENCE

- A. Sekisui Diagnostics L3K Acetaminophen package insert, Sekure Chemistry, May, 2015.
- B. Analyte Attribute Template, Architect/Aeroset System, Abbott Laboratories, Inc.