**Purpose** To provide detailed lab specific information for Acetaminophen performed at Einstein Medical Center Philadelphia and Einstein Medical Center Elkins Park.

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| **Intended Use** | The MULTIGENT Acetaminophen assay is intended for the quantitative determination of acetaminophen in human serum or plasma on the ARCHITECT *c* Systems. |

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| **Clinical Utility** | Acetaminophen (paracetamol) is used as an analgesic in many different formulations. While therapeutic doses rarely cause adverse side effects, the effect of long term treatment with acetaminophen is unclear. Cases have been reported where chronic excessive use of acetaminophen led to hepatotoxicity and nephrotoxicity. In cases of acute overdosage, acetaminophen can cause severe hepatic damage leading to hepatic failure if untreated.The management of acetaminophen overdose requires early recognition of the drug in the bloodstream. Toxicity is generally reported at concentrations over 200 mcg/mL. N-acetylcysteine has been used as an antidote in conjunction with intensive support care. Early diagnosis of acetaminophen-induced hepatotoxicity is important since initiation of therapy within 8 hours of ingestion lessens the potential for hepatic injury, and decreases the mortality rate. |

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| **Methodology** | Enzymatic/Colorimetric |

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| **Specimen Information** | **Sample Type** | **Tube Color(s) Anticoagulant(s)** | **Minimum Volume** | **Stability** |
| Serum | Glass or Plastic:Serum with or without gel barrier | Standard: 10 μL | 14 days at 4-8°C45 days at ≤ -20°C |
| Plasma | Glass or Plastic:Lithium heparin (with or without gel barrier) Sodium heparin | Standard: 10 μL | 14 days at 4-8°C45 days at ≤ -20°C |

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| **Special Instructions and Storage** | Separated samples may be stored for up to 14 days at 4 to 8°C prior to being tested. If testing will be delayed more than 14 days, separated samples may be stored frozen at ≤ -20°C for up to 45 days. Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing. |

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| **Specimen Limitations***Do not use the following:* | None |  |

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| **Reagents** | Reagent Kit 03R11-20 MULTIGENT Acetaminophen is supplied as a liquid, ready-to-use, two-reagent kit which contains R1 and R2. Refer to Package Insert for chemical composition.Before use, invert several times, avoiding the formation of bubbles. Pour the R1 Reagent bottle into a 20mL plastic wedge and label. Pour both of the R2 reagent bottles into a 20mL plastic wedge and label. When either the R1 or the R2 reagent cartridge becomes empty, replace both cartridges.Reagent stability is 8 days if the reagent is uncapped and onboard. Reagent onboard use should be no more than 192 hours. Unopened reagents are stable until the expiration date when stored at 2 to 8°C. Do not use components beyond the expiration date. Do not mix materials from different kit lot numbers. |

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| **Calibration** | Calibration is stable for approximately 24 hours. Calibration is required with each change in reagent lot number. Verify the calibration curve with at least two levels of controls according to the established quality control requirements for your laboratory. Refer to CH03-100 Appendix A for Calibrator material.  |

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| **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. Refer to Chemistry QA Manual Quality Control Procedure CHQA01-002 and appendix CHQA01-002 Appendix A, CHQA01-002 Appendix B, CHQA01-002 Appendix C for detailed instructions, materials in use and LIS QC accession numbers. |

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| **Procedure** | For a detailed description of how to run an assay on an ARCHITECT *c* System, refer to Section 5 of the instrument-specific operations manual. |

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| **Limitations of Procedure** | “Interference from N‐acetylcysteine (NAC) was evaluated on a commercially available analyzer. The concentration of NAC at which acceptable acetaminophen results were obtained was 1500 mg/L NAC in values from a 109 μg/mL acetaminophen sample, tested two hours after the addition of NAC to a serum pool.Testing performed on patients who have not received NAC, such as those drawn initially to diagnose potential acetaminophen overdose, are not impacted.Testing performed on patients who have received NAC therapy have the potential to be impacted. Falsely depressed acetaminophen results could lead a healthcare provider to incorrectly believe that further treatment for acetaminophen toxicity is not necessary. * Hemolysis: Cancel and request recollect when Hemolysis Index >200. Do not report 2+ grossly hemolyzed samples.
* Icterus: Dilute to reduce icterus when Icterus Index >16
* Lipemia: Centrifuge or dilute samples when Lipemia index >200.
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| **Sensitivity**  | The Limit of Quantitation (LOQ) for the MULTIGENT Acetaminophen assay was calculated to be 3 mcg/mL.  |

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| **Analyte Specs:*** **Specificity**
* **Precision**
* **Interfering Substances**
 | Refer to Package Insert for Specific Performance Characteristics. |

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| **Dilution**  | Specimens with acetaminophen values exceeding 230 mcg/mL are flagged and may be diluted using the Manual Dilution Procedure. A manual dilution can be performed on patient samples with acetaminophen concentrations reported as greater than 230 mcg/mL by making a dilution of the specimen with saline before pipetting the sample into the sample cup. The dilution must be performed so the diluted test results read greater than the assay sensitivity of 3 mcg/mL. The operator must enter the manual dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor. The printed result is the reportable result if no errors are present. If the operator does not enter the manual dilution factor, the printed result must be multiplied by the manual dilution factor before reporting the result. |

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| **Unit of Measure** | mcg/mL |

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| **Analytical Measurement Range** | The Analytical Measurement Range of the assay is 3 to 230 mcg/mL.  |

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| **Results** |  |  |  |
| **Reference Range** | 10-25 mcg/mL |  |
| **Alert Values** | ≥ 50 mcg/mL |  |
| **Reporting Results** | Results are interfaced to the LIS and verified by the tech or auto-verified by the LIS as appropriate.Results lower than 3 mcg/mL are reported as <3 mcg/mL.Results higher than 2300 mcg/mL are reported as >2300 mcg/mL. |

**Approval Signatures:**

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| **Date** | **Printed Name** | **Signature** |
| 1/29/2016 | Vanessa Rawlings, MHA, MTElkins Park Supervisor |  |
| 1/29/2016 | Jennifer Lore, MFS, MTChemistry Supervisor |  |
| 1/29/2016 | Nancy A. Young, M.D., FCAPMedical Director |  |

**History Review**

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| **Date Reviewed** | **Reviewed By** | **Revisions** |
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