Addendum to High Troponin Values Procedure

A. High Troponin Value Issue

1. Per medical Device Recall letter from Beckman Coulter, dated August 5, 2021 there is a potential intra-assay carryover risk with the Access hs TnI assay (previously identified in IPN-000328 dated April 2020).

2. There is a risk of significant carryover into a different reagent pack then the test is performed immediately after a sample with a cTnI concentration of > 270,000 pg/ mL and uses the same reagent pipettor.

3. Typically, cTnI concentrations > 270,000 pg/mL are not routinely observed in patients presenting to the emergency department with chest pain. Although the risk of carryover is rare, it can affect the results of all subsequent samples that are tested from the affected pack.

4. This carryover does not affect any other Access assay.

B. Procedure for High hs TnI Values

1. An Access hs Troponin pack that is sampled immediately after a > 270,000 pg/ mL cTnI sample, using the same reagent pipettor, may demonstrate intra-assay carryover, which will impact the results for all subsequent samples tested from that reagent pack.

2. Staff will receive an out of linearity value of > 23,000 pg/ mL. Patient results may be released, per protocol as > 23,000 pg/mL.

3. Prior to performing any additional hs Troponin testing on the instrument with the out of linearity value, staff will need to evaluate the actual hs TnI result.

4. Staff will perform a 1:10 dilution on the affected sample. If the value is < 270,000 mg/ mL there is no further action required. If the value is > 270,000 mg/ mL, further action will be required.

C. Procedure for Values > 270,000 mg/ mL

1. Remove and discard all open Access hsTnI reagent packs.

2. Load a new Access hsTnI reagent pack onto the analyzer.

3. Perform QC

a. If the QC is within normal limits, patient testing may resume on that analyzer.

b. If the QC is outside normal limits, contact Beckman Coulter Customer Technical support (1-800-854-3633) for further instructions.

4. If any patient testing were performed after the >270,000 result on the removed reagent pack, staff will need to re-test that patient sample.