Practice 005:

OOS or NOTE 1: At any time during the LI. QA Laboratory Supervisor Notified Manager may issue Alerts to principals Ouestionable potentially affected. **Result Detected** NOTE 2: Following Initial Investigation, the OOS or Questionable Result may be SEEK ASSIGNABLE CAUSE (AC) accepted as valid with no further Review for obvious errors investigational measurement or testing. Take corrective action. No YES AC Found? LIR Required. NO **Initial Investigation** - Initiate LIR Declare Original Results Form and conduct Initial Investigation invalid. YES AC Found? Evaluate potential NO impact on other samples Is Resample Investigational Measurements -NO Prepare & execute Investigational Needed? Measurements Protocol Repeat tests to replace invalidated results NO YES YES AC Found? NO Complete. Approve. Conduct **Retesting** - Establish Retest Issue & Close LIR Form Protocol and Conduct Approved **Re-sampling** Retest Site Quality Team on behalf of the Site Quality Review Team If OOS is confirmed: determines and executes required notification to • Notify SQRT any Regulatory • Issue all required Alerts Authorities, including • Initiate any further required investigations possible NDA-Field

Alert Report to FDA

Figure 1: Laboratory Investigation (LI) Process Flowchart

Figure 2:

Decision Tree for Unidentified Peaks

