Clinical Chemistry Analyzer MDRs

Industry Roundtable

June 2, 2016

- JJE Product code = analyzer, chemistry (photometric, discrete), for clinical use

- DCTD receives ~5000 MDRs for the JJE product code per year
  - ~2-10 injuries/week
  - ~2-7 deaths/year

- Of the thousands of MDRs submitted, 50-75% are incorrectly submitted under JJE
- These MDRs must be individually reassigned to the correct product codes
- This is extremely labor intensive for our analysts

Examples

A discordant, falsely elevated Troponin I result was obtained on one patient sample on an [INSTRUMENT NAME]. The discordant result was not reported to the physician(s). The sample was repeated three times on the same instrument, resulting lower all three times. One of the repeat results was reported to the physician(s). The cause of the discordant, falsely elevated troponin result on one patient sample is unknown. The instrument is performing according to specifications. Quality controls were within range at the time the discordant result was obtained and system maintenance had been performed in accordance with the system manual. The customer runs all positive Troponin patient samples in duplicate and the instrument is scheduled for replacement with an [ALTERNATE INSTRUMENT NAME].

This MDR would be more appropriately submitted under the troponin assay product code.

Examples

The customer stated that they received an erroneous result for one patient sample tested for troponin. The customer did not have issues with any other patient samples. The sample initially resulted as 0.348 ng/ml and this value was reported outside of the laboratory. The sample was repeated two times, each time resulting with a value below the measuring range of the assay and accompanied by a data flag. The repeat result was believed to be correct.

This MDR would be more appropriately submitted under the troponin assay product code.

Examples

"The customer reports that one patient sample generated an initial [INSTRUMENT NAME] Toxo IgG Assay result of 56.42 IU/mL. The sample retested at 0.05 and 0.07 IU/mL. The customer considers the initial result to be a false positive result."

This MDR would be more appropriately submitted under the Toxo IgG assay product code.

Discussion/Questions

Thank you!