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Patient Impact Assessment: TPS 3.5

DEFICIENCIES:

D5403 Finding #2, D5481 Finding #2, D5791 Finding #2, D5791 Finding #3, D6102, D6115

INVESTIGATION:

The laboratory agrees that its descriptions of prior analyses were lacking sufficient detail to explain the conclusions submitted in its original response.

Upon a review of that response, including the entirety of the prior analysis of TPS 3.5 QC data and patient test result distributions for all analytes during the time period examined, the laboratory made note of poor QC performance throughout. Therefore, the laboratory conducted an expanded retrospective analysis for 2014 and 2015 QC data. This data is presented at Ex. FF, Tabs 1-12. The laboratory noted multiple and recurrent time periods (across all analytes tested) of abrupt shifts in QC target means, high rates of 1-2s QC rule failures, and QC CVs far exceeding limits for a stable testing process.

PATIENT IMPACT:

Although the magnitude of QC deviations from target means does not necessarily reflect the exact nature and magnitude of bias on patient results because of differences in matrices, the QC failures identified by this comprehensive retrospective analysis reflect a global and long-term failure of the quality control program for this instrument, as well as failures of related quality assurance procedures that should have alerted the laboratory to correct such an unstable process. Therefore, the laboratory has concluded that there is a possible patient impact for every test reported from the laboratory's TPS 3.5 instruments.

CORRECTIVE ACTION:

The fraction of patient results truly impacted, and the nature and magnitude of any effect, are unknown. Out of an abundance of caution, the laboratory has voided all patient test results reported from the TPS 3.5 instruments. Many corrected reports have been transmitted, and the remainder are being transmitted. (Ex. KK). Transmission will be complete by March 31, 2016. The remainder of the transmittals and confirmations of receipt will be provided to CMS under separate cover.