

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0307529	(X3) Date Survey Completed 12/20/2023
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State 3443 Dickerson Road, Suite 760, Nashville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5479	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's instructions-for-use (IFU), and review of the laboratory information system (LIS) quality control (QC) records, the laboratory failed to follow manufacturer's QC range specifications for two of two lots of Quantimetrix Dropper Plus Point-of-Care Urinalysis Dipstick Control material used by the laboratory's urinalysis testing system. The Findings include: 1. Observation of the laboratory on 12/20/23 at 8:45 a.m. revealed the following: - Siemens Clinitek Status analyzer (SN: ST126179) for reading Siemens Multistix 10 SG reagent strips (Lot: 301081) used for patient urinalysis testing. - Quantimetrix Dropper Plus Point-of-Care Urinalysis Dipstick Control material (Lots: 204411 and 204412) used for quality control of the Siemens Clinitek Status analyzer with Multistix 10 SG reagent Strips. 2. Review of the manufacturer's IFU revealed the following: - The Multistix 10 SG package insert states "Compare QC results to the QC manufacturer's acceptable results list." - The Quantimetrix Dropper Plus Point-of-Care Urinalysis Dipstick Control package insert states Level 1 (Lot: 204411) QC range for Specific Gravity is 1.015 to greater than 1.030. Level 1 QC range for pH is 5.0 - 6.5. - The Quantimetrix Dropper Plus Point-of-Care Urinalysis Dipstick Control package insert states Level 2 (Lot: 204412) QC range for Glucose is Trace to 2+. 3. Review of the laboratory's Copia LIS QC records from 12/18/23 provided by email from the technical consultant on 12/20/23 at 11:57 a.m. revealed the laboratory's in-</p>

use lower limit for Level 1 Specific Gravity (1.010), the upper limit for Level 1 pH (6.5), and the upper limit for Level 2 Glucose (4+) was outside the manufacture's QC range specifications.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of testing personnel (TP) competency assessment records, review of proficiency testing (PT) records, lack of records, and staff interview, the technical consultant failed to ensure assessment of blind testing or external proficiency testing was included as part of the competency assessment for one of two testing personnel performing complete blood count (CBC) patient testing in 2021, 2022, and 2023. The finding include: 1. Review of the Form CMS-209 revealed two testing personnel performing CBC patient testing. 2. Review of the laboratory's competency assessment records for TP1 revealed the following : - The laboratory's competency assessment form item "5" is stated as "Assessment of test performance through testing blind specimens or CAP". - Assessment item 5 performed for TP1 on 5/26/21 states "Blind sample or MLE#" used is "M-1 2021". - Assessment item 5 performed for TP1 on 5/18/22 states "Blind sample or MLE#" used is "2022 MLE M1". - Assessment item 5 performed for TP1 on 5/30/23 states "Blind sample or MLE#" used is "2023 MLE M1". 3. Review of the laboratory's Medical Laboratory Evaluation (MLE) PT records revealed the following: - 2021 MLE-M1 attestation statement lists neither TP1 nor TP2 as the testing personnel. - 2022 MLE-M1 attestation statement lists TP2 as the testing personnel. - 2023 MLE-M1 attestation statement lists TP2 as the testing personnel. - TP1 is not listed as the testing personnel for any of the MLE PT events. 4. There were no other records of assessment of test performance for TP1 for surveyor review. 5. An interview with the technical consultant on 12/20/23 at 11:30 a.m. confirmed the competency assessment records for TP1 and MLE PT records did not agree and neither internal blind testing nor external proficiency testing was included as part of the competency assessment for TP1 in 2021, 2022, and 2023.