| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>44D1052600 | **(X3) Date Survey Completed**<br><br>06/01/2023 |
|---|---|---|
| **Name of Provider or Supplier**<br><br>Tennessee Oncology, Pllc | **Street Address, City, State**<br><br>2200 E Third Street, Suite 100, Chattanooga, 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** |
|---|---|
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS Laboratory Personnel Report (CLIA) (CMS 209), laboratory policy, testing personnel (TP) records, and interview with the technical consultant, the laboratory failed to follow the policy for personnel competency assessment for one of four testing personnel in 2022. The findings include: 1. Review of CMS 209 report revealed four testing personnel performing patient testing for complete blood counts and manual blood smear differentials. Testing personnel three was a new testing person since last survey with documented hire date of 01.10.2022. 2. Review of the laboratory's policy titled, "Competency Testing on Laboratory Personnel" stated, "During the first year of an individual's duties, competency must be assessed after initial training and semiannually". 3. Review of testing personnel competency assessment records revealed no documentation of semiannual competency assessment for testing personnel three in 2022. 4. Interview with the technical consultant on June 1, 2023 at 11:45 a.m. confirmed the laboratory failed to follow its policy for testing personnel competency assessment in 2022. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper |

| | |
|---|---|
| | use.<br><br>This STANDARD is not met as evidenced by:<br>CITATION NUMBER ONE: Based on observation of the laboratory, review of manufacturer complete blood count (CBC) quality control package insert and interview with the technical consultant, the laboratory failed to label CBC quality control vials with corrected expiration date on the date of the survey (06.01.2023). The findings include: 1. Observation of the laboratory on June 1, 2023 at 8:50 a.m. revealed a Sysmex XN-430 CBC instrument (serial #11141) and a Sysmex XN-550 CBC instrument (serial # 16435) in use for patient testing. Also observed were three levels of Sysmex XN-L CBC controls (Lot 3125) that were not labeled with corrected expiration date. 2. Review of the manufacturer quality control package insert revealed the following statement: "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being re-capped." 3. Interview with the technical consultant on June 1, 2023 at 8:55 a.m. confirmed the laboratory had not labeled CBC quality control vials with corrected expiration date on the date of the survey (06.01.2023). Word Key C = Celsius<br>CITATION NUMBER TWO: Based on observation of the laboratory and interviews with the technical consultant, the laboratory failed to label three coplin jars of QuickLink stains used in manual blood smear differential patient testing in 2023. The findings include: 1. Observation of the laboratory on June 1, 2023 at 8:45 a.m. revealed a microscope on the counter and three coplin jars of QuickLink Stains (QuickLink III Fixative Solution, QuickLink III Solution I, and QuickLink III Solution II) that were not labeled in use for performing manual blood smear differential patient testing. 2. Interview with the technical consultant on June 1, 2023 at 8:55 a.m. confirmed the QuickLink stains (QuickLink III Fixative Solution, QuickLink III Solution I, and QuickLink III Solution II) had been poured from the original bottles into the coplin jars. 3. Interview with the technical consultant on June 1, 2023 at 11:45 a.m. confirmed the laboratory failed to label the three coplin jars containing QuickLink III Fixative Solution, QuickLink III Solution I, and QuickLink III Solution II with content, lot number and expiration date on the date of the survey (06.01.2023). |