

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2150401	(X3) Date Survey Completed 12/02/2024
Name of Provider or Supplier Redmed Of Arlington, Llc	Street Address, City, State 5389 Airline Rd, Arlington, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation and staff interview, the laboratory failed to ensure microtainer tubes used to collect fingerstick samples for Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) testing were not expired on the date of the survey (12/02/24). The findings include: 1. Laboratory observation on 12/02/24 at 8:43 a.m. revealed the Sysmex XP-300 instrument (serial #C4845) used for performing patient testing for CBC w/Diff. Microtainer tubes used for collecting fingerstick patient samples for CBC w/Diff were observed with a lot number of 22E4466 and an expiration date of 05/31/24. 2. The technical consultant confirmed the survey findings during an interview on 12/02/24 at 1:30 p.m.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's quality control (QC)</p>

records, review of daily activity logs, staff interviews and review of the Quality Assurance/Quality Assessment form, the laboratory's quality assessment process was not effective in detecting and correcting problems with management of QC files, resulting in performance and evaluation of daily QC against incorrect QC limits for four of eighteen testing dates since the new QC lot started on 11/13/24 with 20 patients potentially affected. The findings include: 1. Laboratory observation on 12/02/24 at 8:43 a.m. revealed the Sysmex XP-300 instrument (serial # C4845) used for performing patient testing for CBC w/Diff. 2. A review of the laboratory's current QC lot numbers and corresponding records revealed the following: The current lot numbers of QC were 43030710, 43030711, and 43030712. The lot numbers and corresponding QC limits were configured into the instrument under QC files four, five, and six, respectively. The first date of use was 11/13/24. 3. A review of the laboratory's previous QC lot numbers and corresponding records revealed the following: The previous QC lot numbers were 42190710, 42190711, and 42190712. The lot numbers and corresponding QC limits were configured into the instrument under QC files one, two, and three, respectively. 4. A review of the laboratory's daily QC records revealed the following: All three levels of QC for the dates of 11/15/24, 11/16/24, 11/17/24, and 11/22/24 were performed and evaluated for acceptability using the QC files and corresponding ranges for the previous lot numbers (42190710, 42190711, and 42190712-programmed into QC files one, two, and three). 5. A review of daily activity logs revealed patient testing for CBC w/Diff performed on dates when the QC was performed and evaluated for acceptability using the wrong QC files and limits as follows: 11/15/24 Patient identification numbers: 260051, 260052, 287726, 308733, 240770 11/16/24 Patient identification numbers: 200456, 152494, 281611, 296755, 248731, 305818, 84754, 289242 11/17/24 Patient identification numbers: 250944, 305876, 283633, 305877, 79785 11/22/24 Patient identification numbers 90015 and 207247. 6. Testing person one stated during an interview on 12/02/24 at 12:10 p.m. that the laboratory discards old QC when the new QC is placed into use and confirmed the current QC lots (43030710, 43030711, and 43030712) were performed and evaluated for acceptability using the QC files for the previous lot numbers (42190710, 42190711, and 42190712) for the dates of 11/15/24, 11/16/24, 11/17/24, and 11/22/24. 7. A review of the Quality Assurance/Quality Assessment form dated 12/02/24 revealed review of both the old lot numbers (4219) and the new lot numbers (4303). There was no documentation that the issue with performing QC for the current lot in the control files for the previous lot was identified. No corrective action was documented. 8. The technical consultant confirmed the survey findings during an interview on 12/02/24 at 1:30 p.m.