Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0052671	02/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hamilton Hospital Laboratory	901 W Hamilton Po Box 158, Olney, TX	

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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, manufacturer's instructions, patient test records, and staff interview, the laboratory failed to ensure patient lactic acid specimens were received and centrifuged within 15 minutes as required by manufacturer's instructions for one of five patients reviewed in 2025 (random sampling January). Findings included: 1. Review of the laboratory's Lactic Acid Procedure stated: "Specimen: Storage: Stability: 1. Tubes of Sodium Fluoride (Gray tube) blood are to be kept closed at all times and in a vertical, stoppered position. Keep samples on ice after drawing until separation from cells. 2. Tubes must be separated from contact with cells within 15 minutes of sample collection, [sic] and analyzed without delay. 3. Plasma samples separated from cells are stable stored at: RT (15-25C) 8 Hours Ref (2-8C) 14 Days Frn (-20C) 1 Month" 2. Review the manufacture's information sheet for lactic acid revealed: "SPECIMEN TYPE OF SPECIMEN Biological fluid samples should be collected in the same manner routinely used for any laboratory test.1 Freshly drawn plasma or cerebrospinal fluid are the preferred specimens. Chill the specimen immediately ... SPECIMEN STORAGE AND STABILITY 1. Tubes of blood are to be kept closed at all times and

	in a vertical, stopper-up position. Keep samples on ice. Plasma should be physically separated from contact with cells within 15 minutes of sample collection, and analyzed without delay. 2. Plasma samples separated from cells are stable stored at: +15C to +25C up to 8 hours, +2C to +8C up to 14 days, -20C up to month ... SPECIMEN HANDLING Special instructions for specimen handling as designated by this laboratory: - Gray Tube on ice immediately after Draw [sic] (Not Before) - No Tourniquet - Separation within 15 min." 3. Review of patient test records revealed the laboratory did not ensure patient lactic acid specimen's plasma were received and centrifuged within 15 minutes as required by the manufacturer for the following patients in January 2025 (random review): Patient M/R#: 017335 Collection date: 01 /20/2025, collection time: 1105 hours, received time: 1125 hours, resulted time: 1159 hours, time elapsed from collection to receipt was 20 minutes The laboratory failed to ensure patient lactic acid specimen's plasma were received and centrifuged within 15 minutes as required by the manufacturer. There was no documentation of the specimens separated plasma being stored in the refrigerator if the specimens could not be tested immediately after centrifugation, as stated by the manufacturer. 4. During an interview on 02/06/2025 at 12:35 p.m., the Technical Consultant-2 confirmed the laboratory failed to ensure patient lactic acid specimen's plasma were received and centrifuged within 15 minutes. Word Key: RT- room temperature Ref- refrigerated Frn- frozen min- minutes C- Celsius M/R#- medical record number II. Based on review of manufacturer's instructions, patient test records, and staff interview, the laboratory failed to ensure patient ammonia specimens were received and centrifuged within ten minutes as required by manufacturer's instructions for two of five patients reviewed in 2024 (random sampling December). Findings included: 1. Review the manufacture's information sheet for ammonia stated: "SPECIMEN ... SPECIMEN STORAGE AND STABILITY Tubes should be filled completely, mixed gently by inversion, placed on ice, centrifuged immediately for 10 minutes at an RCF of 1500G and analyzed within 30 minutes. Samples should not be frozen. The tubes should be tightly stoppered at all times." 2. Review of patient test records revealed the laboratory did not ensure patient ammonia specimen's plasma were received and centrifuged within ten minutes as required by the manufacturer for the following patients in December 2024 (random review): Patient M/R#: 039734 Collection date: 12/04/2024, collection time: 0922 hours, received time: 0949 hours, resulted time: 1108 hours, time elapsed from collection to receipt was 27 minutes Patient M/R#: 039734 Collection date: 12/09/2024, collection time: 1608 hours, received time: 1628 hours, resulted time: 1650 hours, time elapsed from collection to receipt was 20 minutes The laboratory failed to ensure patient ammonia specimen's plasma were received and centrifuged within ten minutes as required by the manufacturer. 4. During an interview on 02/06/2025 at 12:35 p.m., the Technical Consultant-2 confirmed the laboratory failed to ensure patient ammonia specimen's plasma were received and centrifuged within ten minutes. Word Key: M/R#- medical record number
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct observation, review of hematology quality control (QC) package inserts, laboratory policy, and confirmed in interview, the laboratory failed to have a system in place to ensure three of three lots of QC reagent was not utilized in excess of 18 times within 16 days according to the package insert. Findings included: 1. During a tour of the laboratory on 02/05/2025 at 1:52 p.m., the surveyor observed the following control material stored in the refrigerator: 1 Coulter 6C Cell Control; level 1 control lot #A65072-AB; manufacture expiration date: 02/08/2025; open date: 01/22 /2025 1 Coulter 6C Cell Control; level 2 control lot #A62073-AB; manufacture expiration date: 02/08/2025; open date: 01/22/2025 1 Coulter 6C Cell Control; level 3 control lot #A62087-AB; manufacture expiration date: 02/08/2025; open date: 01/22 /2025 2. Review of the package insert for the Coulter 6C-ES Cell Control stated "* Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days." 3. Review of laboratory policy "DxH600 Startup and Quality Control" stated: "Coulter 6 Cell: Unopened: Good until expiration on bottle Opened: 16 Days **Based on opening at least 18 times in 16 days" 4. During an interview on 02/05/2025 11:45 am, Testing Person (TP-6) was asked whether the laboratory had a mechanism in place to track the number of times control material was used (not to exceed 18 times within 16 days), she stated that she did not know how many times the QC was analyzed and that QC expired after 16 days. The number of times the control material was analyzed per lot number could not be assessed to ensure it was not utilized in excess of 18 times within 16 days.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: I. Based on review of laboratory's quality control (QC) policy, ACL Elite QC data, and in interview with staff, the laboratory failed to ensure their control procedures detected immediate error for two of two sets of current lot numbers (January through July 2024). Findings included: 1. Review of the laboratory's "Quality Control Policy and Procedure" policy stated: "Establishing the Value Range: Unassayed 1. Perform the analyte over a period of days. Perform at least 20 data points over a 20 to 30 day period. * Perform in conjunction with previous lot number of QC. 2. Include: a. Procedural Variations b. Different testing personnel c. Perform if possible, different reagent lots d. Beginning of bottle vs. end of bottle. e. Perform if possible, 2 different QC bottle openings. 3. Calculate the mean and the standard deviation of the result. 4. Evaluate the CV% with package insert for acceptable ranges ... QC Mean Calculation: Unassayed The purpose of obtaining 20 data points for unassayed QC is to quantify normal variation and establish a mean. Rules: If one or two data points are too high or too low for the set of data, they should not be included in the calculation. These are called, "Outliers". If there are more than 2 outliers in the 20 data points, there is a

problem with the data and it should not be used. Identify and resolve the problem and repeat the data collection process of 20 more data points. The New Mean is established and ready for use in evaluating the new QC charts. Establishing a New SD: The SD used for the QC chart should reflect the over-all imprecision of a method. That is, all the variables in a method should be part of the data from which the SD is calculated. The 20-30 data sample SD is not enough variable to use for the SD. 1. Using the CV from the previous lot or lots in combination with the new mean will be used to establish a new SD. 2. The CV that measures relative precision should be the same consistently on the same instrument from lot to lot. No significant deviation is usually noticed. Formula: %CV = SD X 100 + mean 3. SD(New) = % CV(Old) X Mean(New)" 2. Review of ACL Elite hematology analyzer "QC STATISTIC AND LEVEY-JENNINGS PLOT REPORT" (random review 01/2024 through 07/2024) revealed the ranges used did not detect immediate error, as follows: A) Prothrombin Time (PT) control Normal Level: Lot #N0431103, expiration date 04/30/2026 High Abnormal Level: Lot #N0331001, expiration date 04/30/2026 Laboratory PT QC ranges used for day-to-day acceptability: 02/01/2024 through 03/02/2024 Normal Level Target Mean: 11.9 Target SD: 0.800 (1SD) Range: 10.300-12.700 A handwritten note to the side (dated 3/14/23 [sic]) stated: "LTD: 12.0 SD: 0.87 Cur: 12.1 SD: 1.9 Adjust Mean to LTD=12.0" Laboratory PT QC ranges used for day-to-day acceptability: 04/10/2024 through 05/10/2024 Normal Level Target Mean: 12.0 Target SD: 0.800 (1SD) Range: 10.400-12.800 A handwritten note to the side (dated 5 /10/20) stated: "LTD: 11.9 SD: 0.78 Cur: 11.8 Adjust to LTD=11.9" Laboratory PT QC ranges used for day-to-day acceptability: 05/01/2024 through 05/31/2024 Normal Level Target Mean: 11.9 Target SD: 0.800 (1SD) Range: 10.300-12.700 A handwritten note to the side (dated 6/9/24) stated: "LTD: 11.9 SD: 0.74 Current: 11.7 SD: 0.12 Adjusted to 11.8" Laboratory PT QC ranges used for day-to-day acceptability: 01/01/2024 through 01/31/2024 Abnormal High Level Target Mean: 33.7 Target SD: 3.600 (1SD) Range: 26.500-40.900 A handwritten note to the side (dated 2/22/24) stated: "LTD: 33.6 SD: 2.2 Current: 33.3 SD: 1.67 Adjust to current 33.3" Laboratory PT QC ranges used for day-to-day acceptability: 03/01/2024 through 03/31/2024 Abnormal High Level Target Mean: 33.3 Target SD: 3.600 (1SD) Range: 26.100-40.500 A handwritten note to the side (dated 4/13/24) stated: "LTD: 33.1 SD: 2.3 Current: 32.3 SD: 3.6 Adjust to LDT 33.1" Laboratory PT QC ranges used for day-to-day acceptability: 04/10/2024 through 05/10/2024 Abnormal High Level Target Mean: 33.1 Target SD: 3.600 (1SD) Range: 25.900-40.300 A handwritten note to the side (dated 5/10/24) stated: "LTD: 32.9 SD: 2.3 Current: 32.1 SD: 1.69 Adjust to the Mean 32.5" Laboratory PT QC ranges used for day-to-day acceptability: 05/01/2024 through 05/31/2024 Abnormal High Level Target Mean: 32.5 Target SD: 3.600 (1SD) Range: 25.300-39.700 A handwritten note to the side (dated 6/9/24) stated: "LTD: 32.8 SD: 2.3 Current: 31.9 SD: 2.12 Adjusted to 32.35" The laboratory's QC ranges were too wide to detect immediate error. QC was monitored over time monthly, and the mean was adjusted to the LTD, current mean or an average of the LTD and current mean. B) Activated Partial Thromboplastin Time (aPPT) control Normal Level: Lot #N0431103, expiration date 04/30/2026 High Abnormal Level: Lot #N0331001, expiration date 04/30/2026 Laboratory aPPT QC ranges used for day-to-day acceptability: 01/01/2024 through 01/31/2024 Normal Level Target Mean: 29.2 Target SD: 2.000 (1SD) Range: 25.200-33.200 A handwritten note to the side (dated 2 /12/24) stated: "LTD: 29.2 SD: 1.06 Current: 29.1 SD: 0.74 Adjust to current 29.1" Laboratory aPPT QC ranges used for day-to-day acceptability: 02/01/2024 through 03 /02/2024 Normal Level Target Mean: 29.1 Target SD: 2.000 (1SD) Range: 25.100-33.100 A handwritten note to the side (dated 3/14/24) stated: "LTD: 29.3 SD: 1.9 Curr: 29.7 SD: 3.1 Adjust Mean to LTD 29.3" Laboratory aPPT QC ranges used for day-to-day acceptability: 03/01/2024 through 03/31/2024 Normal Level Target Mean:

29.3 Target SD: 2.000 (1SD) Range: 25.300-33.300 A handwritten note to the side (dated 4/13/24) stated: "LTD: 29.4 SD: 1.86 Cur: 29.5 Adjust to LTD 29.4" Laboratory aPPT QC ranges used for day-to-day acceptability: 06/01/2024 through 07 /01/2024 Normal Level Target Mean: 29.4 Target SD: 2.000 (1SD) Range: 25.400-33.400 A handwritten note to the side (dated 7/11/24) stated: "LTD: 29.3 SD: 1.6 Cur: 29 SD: 0.65 Adjusted to the LTD 29.3" Laboratory aPPT QC ranges used for day-to-day acceptability: 01/01/2024 through 01/31/2024 High Abnormal Level Target Mean: 57.7 Target SD: 4.000 (1SD) Range: 49.700-65.700 A handwritten note to the side (dated 2/12/24) stated: "LTD: 57.4 SD: 1.6 Current: 56.6 SD: 1.08 Adjusted to the mean of LDT + current 57.0" Laboratory aPPT QC ranges used for day-to-day acceptability: 02/01/2024 through 03/02/2024 High Abnormal Level Target Mean: 57.0 Target SD: 4.000 (1SD) Range: 49.000-65.000 A handwritten note to the side (dated 3/14/24) stated: "LTD: 57.1 SD: 2.6 Curr: 55.8 SD: 2.8 Adjusted mean to 56.45" Laboratory aPPT QC ranges used for day-to-day acceptability: 03/01/2024 through 03/31/2024 High Abnormal Level Target Mean: 56.5 Target SD: 4.000 (1SD) Range: 48.450-64.450 A handwritten note to the side (dated 4/13/24) stated: "LTD: 57 SD: 2.47 Cur: 56.6 Adjust to LDT 57" Laboratory aPPT QC ranges used for day-to-day acceptability: 06/01/2024 through 07/01/2024 High Abnormal Level Target Mean: 57.0 Target SD: 4.000 (1SD) Range: 49.000-65.000 A handwritten note to the side (dated 7/11/24) stated: "LTD: 56.8 SD: 2.12 Current: 55.6 SD: 1.3 Adjusted to the Mean: 56.2" The laboratory's QC ranges were too wide to detect immediate error. QC was monitored over time monthly, and the mean was adjusted to the LTD, current mean or an average of the LTD and current mean. C) D-Dimer control Low Level: Lot #B35766, expiration date 06/30/2025 High Level: Lot #B35766, expiration date 06 /30/2025 Laboratory D-Dimer QC ranges used for day-to-day acceptability: 01/01 /2024 through 01/31/2024 Low Level Target Mean: 346 Target SD: 41.5 (1SD) Range: 263.000-429.000 A handwritten note to the side (dated 2/12/24) stated: "LTD: 338 SD: 37.4 Current: 352 SD: 17.6 Adjust to 345" Laboratory D-Dimer QC ranges used for day-to-day acceptability: 02/01/2024 through 03/02/2024 Low Level Target Mean: 345 Target SD: 41.5 (1SD) Range: 262.000-428.000 A handwritten note to the side (dated 3/14/24) stated: "LTD: 339 SD: 39.7 Current: 340 SD: 14.3 No Adjustment" Laboratory D-Dimer QC ranges used for day-to-day acceptability: 03/01 /2024 through 03/31/2024 Low Level Target Mean: 345 Target SD: 41.5 (1SD) Range: 262.000-428.000 A handwritten note to the side (dated 3/14/24) stated: "LTD: 344 CV: 11.6 Cur: 369 CV: 9.58 Adjust to 357" Laboratory D-Dimer QC ranges used for day-to-day acceptability: 01/01/2024 through 01/31/2024 High Level Target Mean: 650 Target SD: 51.5 (1SD) Range: 547.000-753.000 A handwritten note to the side (dated 2/12/24) stated: "LTD: 652 SD: 51.5 Current: 697 SD: 38.1 Adjust to 675" The laboratory's QC ranges were too wide to detect immediate error. QC was monitored over time monthly, and the mean was adjusted to the LTD, current mean or an average of the LTD and current mean. 3. During an interview on 02/05/2025 at 4: 25 p.m., the Technical Consultant-2 stated that QC was reviewed monthly using the Levey-Jennings from the previous month. She stated that she would compare the life to date mean to the current mean and adjust the next month's mean to the LTD, current mean or an average of the LDT and current. This confirmed the above findings. Word Key: SD- standard deviation CV- coeffiecient of variation LTD- life to date Cur/curr- current II. Based on review of laboratory's quality control (QC) policy, manufacturer's instructions, Beckman Coulter DXC-600i QC data, and in interview with staff, the laboratory failed to ensure their control procedures detected immediate error for two of two sets of current lot numbers (random analyte sampling November 2024-February 2025). Findings included: 1. Review of the laboratory's "Quality Control Policy and Procedure" policy stated: "Establishing the Value Range: Assayed 1. May use the manufacturer's range for beginning analysis, but range must

be established with in-house study. 2. Perform the analyte over a period of days. Perform up to 5 data points over a 5-day period, if possible. *Perform in conjunction with previous lot number of QC. 3. Include: a. Procedural Variations b. Different testing personnel c. Perform it possible, different reagent lots d. Evaluate beginning bottle values vs. end of bottle values." 2. Review of the MAS Alcohol Ammonia instructions for use stated: CONTROL RANGES ... All values have been assigned with instruments and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned ranges. Expected values may vary slightly with different reagent and/or methodologies used. Refer to the included table for values obtained for specific systems. Values listed are specific for this lot of control only. Good laboratory practice suggests that each laboratory establish its own parameters ... QUALITY CONTROL All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements." Review of the MAS Liquimmune instructions for use stated: "INTENDED USE ... Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument ... CONTROL RANGES ... All values have been assigned with instruments and reagents available at the time of assay and expected values may vary with different reagents and/or methodologies. Laboratory established means should fall within the assigned ranges although subsequent instrument, reagent or calibration modifications may invalidate assigned values ... QUALITY CONTROL All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements." 3. Review of the Beckman Coulter DXC-600i analyzer QC data (random review November 2023 through February 2025) revealed the ranges used did not detect immediate error as follows (random sampling of analytes): A) MAS Alcohol Ammonia assayed control Level 1 Lot# AA25061A; expiration date: 06/30/2025; mean 45.7; range 27.5-63.9 Level 2 Lot# AA25062A; expiration date: 06/30/2025; mean 182; range 146-219 Laboratory Ammonia QC ranges used for day-to-day acceptability: Level 1 Start date: 12/01/2024 End date: 12 /31/2024 Expected Mean: 41 Range: 21.0-61.0 A handwritten note (dated 1/6/25) stated: "LTD: 42 SD: 4.3 Cur: 46 SD: 4.3 Adjusted to LTD 42" Laboratory Ammonia QC ranges used for day-to-day acceptability: Level 1 Start date: 01/01/2025 End date: 02/04/2025 Expected Mean: 42 Range: 22.0-62.0 Laboratory Ammonia QC ranges used for day-to-day acceptability: Level 2 Start date: 11/01/2024 End date: 11/30 /2024 Expected Mean: 179 Range: 143.0-215.0 A handwritten note (dated 12/7/24) stated: "LTD: 182 CV: 3.1 Cur: 184 CV: 4.0 Adjusted to LTD 182" Start date: 01/01 /2025 End date: 02/04/2025 Expected Mean: 182 Range: 146.0-218.0 The laboratory's QC ranges were too wide to detect immediate error. QC was monitored over time monthly, and the mean was adjusted to the LTD, current mean or an average of the LTD and current mean. B) MAS Liquimmune assayed control Total Thyroxine (TT4) Level 1 Lot# LIA28021A; expiration date: 02/29/2028; mean 8.64; range 6.78-10.5 Level 3 Lot# LIA28023A; expiration date: 02/29/2028; mean 10.9; range 8.74-13.1 Laboratory TT4 QC ranges used for day-to-day acceptability: Level 1 Start date: 11/01 /2024 End date: 02/04/2025 Expected Mean: 8.32 Range: 4.320-12.320 Laboratory TT4 QC ranges used for day-to-day acceptability: Level 3 Start date: 11/01/2024 End date: 11/30/2024 Expected Mean: 10.80 Range: 7.800-13.800 A handwritten note stated: "LTD: 10.75 SD: 0.848 Cur: 11.11 SD: 0.97 Adjusted to the Mean 10.93" Laboratory TT4 QC ranges used for day-to-day acceptability: Level 3 Start date: 12/01 /2024 End date: 12/31/2024 Expected Mean: 10.93 Range: 7.930-13.930 A handwritten note stated: "LTD: 10.86 SD: 0.88 Cur: 11.37 SD: 0.922 Adjusted to the Mean 11.12" Laboratory TT4 QC ranges used for day-to-day acceptability: Level 3 Start date: 01/01/2025 End date: 02/04/2025 Expected Mean: 11.12 Range: 8.120-

	14.120 The laboratory's QC ranges were too wide to detect immediate error. QC was monitored over time monthly, and the mean was adjusted to the LTD, current mean or an average of the LTD and current mean. C) MAS Liquimmune assayed control Thyroid Uptake (TU) Level 1 Lot# LIA28021A; expiration date: 02/29/2028; mean 33.2; range 29.7-36.7 Level 3 Lot# LIA28023A; expiration date: 02/29/2028; mean 58.73; range 52.93-64.23 Laboratory TU QC ranges used for day-to-day acceptability: Level 1 Start date: 11/01/2024 End date: 11/30/2024 Expected Mean: 34.0 Range: 25.70-42.30 A handwritten note (dated 12/7/24) stated: "LTD: 33.7 SD: 1.87 Cur: 33.0 SD: 1.49 Adjusted to the LTD 33.7" Laboratory TU QC ranges used for day-to-day acceptability: Level 1 Start date: 12/01/2024 End date: 02/04/2025 Expected Mean: 33.7 Range: 25.40-42.00 Laboratory TU QC ranges used for day-to-day acceptability: Level 3 Start date: 11/01/2024 End date: 11/30/2024 Expected Mean: 58.8 Range: 47.20-70.40 A handwritten note (dated 12/7/24) stated: "LTD: 58.6 SD: 2.76 Cur: 57.4 SD: 1.48 Adjusted to the Mean 58.0" Laboratory TU QC ranges used for day-to-day acceptability: Level 3 Start date: 12/01/2024 End date: 02/04/2025 Expected Mean: 58.6 Range: 47.00-70.20 The laboratory's QC ranges were too wide to detect immediate error. QC was monitored over time monthly, and the mean was adjusted to the LTD, current mean or an average of the LTD and current mean. 4. During an interview on 02/06/2025 at 11:45 a.m., the Technical Consultant-2 stated that QC was reviewed monthly using the Levey-Jennings from the previous month. She stated that she would compare the life to date mean to the current mean and adjust the next month's mean to the LTD, current mean or an average of the LDT and current. This confirmed the above findings. Word Key: SD- standard deviation CV- coefficient of variation LTD- life to date Cur/curr- current
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions for Cell-Chex Body Fluid Cell Count Control, quality control (QC) records, and confirmed in interview, the laboratory failed to verify the criteria for acceptability for body fluid controls used for monitoring the performance of manual counts of patient body fluids on a hemocytometer for two of two lots in 2023 (February) and six of six lots in 2024 (June, July and November). Findings included: 1. Review of the laboratory's policy " Quality Control Policy and Procedure" stated: "Establishing the Value Range: Assayed 1. May use the manufacturer's range for beginning analysis, but range must be established with in-house study. 2. Perform the analyte over a period of days. Perform up to 5 data points over a 5- day period, if possible. *Perform in conjunction with previous lot number of QC. 3. Include: a. Procedural Variations b. Different testing personnel c. Perform it possible, different reagent lots d. Evaluate beginning bottle values vs. end of bottle values." 2. Review of Cell-Chex Instructions for Use

	revealed: "EXPECTED RESULTS ... Assay range values were established based on+/- 3SD for WBC differential parameters and +/- 2SD for the RBC and WBC parameters. Upon receipt of a new control lot, it is good laboratory practice that an individual laboratory establish its own mean and limits for each parameter. However, the control means established by the laboratory should fall within the expected range specified for the control." 3. Review of "Streck Cell-Chex Hematology Quality Control Log" from February-March 2023 and June-December 2024 revealed the following quality control lot numbers were placed into service and the laboratory failed to verify the criteria for acceptability and cross-check the new quality control lot against the old quality control lot for levels 1 and 2: Level 1: Lot# 2290412; expiration date: 04/17/2023 Level 2: Lot# 2290413; expiration date: 04/17/2023 Level 1: Lot# 40080412; expiration date: 07/08/2024 Level 2: Lot# 40080413; expiration date: 07/08/2024 Level 1: Lot# 41760412; expiration date: 12/24/2024 Level 2: Lot# 41760413; expiration date: 12/24/2024 Level 1: Lot# 42880412; expiration date: 04/14 /2025 Level 2: Lot# 42880413; expiration date: 04/14/2025 4. During an interview on 02/05/2025 at 1:38 p.m., Technical Consultant-2 confirmed the laboratory failed to verify the criteria for acceptability of the control material.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, lack of quality control (QC) records, patient reports, and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for white blood cell differentiation in body fluid samples performed using Cytospin smears for two of two days in 2023 (February and June) and seven of seven days in 2024 (June, July, September and November). Findings included: 1. Review of the laboratory's policy "CSF Cerebral Spinal Fluid Evaluation" stated: "Procedure Notes: Always classified as STAT. 1. Hematology ... c. CSF slide differential 1) Wright's Quick stain -slide preparation a. After preparing hemacytometers (may load two for precaution-four sides) b. Spin Tube 3 for 15 minutes. c. Descant supernatant and use the button to drop one drop on slide. d. Let Air dry. (After a few minutes of air dry, may place on 37 C. box for complete drying) e. Stain using the appropriate instructions for Quick Wright's Stain. f. Dry and perform with oil emersion. 2) Count and differentiate 100 WBCs. Any cell seen in the peripheral blood may be seen in body fluids. Other cells unique to each body cavity may be seen, as well as malignant cells. If the WBC count is very low, you may not be able to find a total of 100 WBC's on the slide to do the differential. In this case, count as many as you can, report the results out in per cent (%) and make a note of how many WBC' s were counted.. [sic] 3) After the differential, scan the entire smear for abnormalities. a. Abnormal Cells b. inclusions c. Clusters or clumps of cells d. intracellular bacteria, yeast or parasites) (Send out for classification) e. Do not report extracellular bacteria-not a sterile sample. 4) The predominant cell seen on the normal differential varies with patient's age. Adults: 70% Lymphocytes and 30 % monocytes Children/neonates: Predominately monocytes 5) Neutrophils rarely seen unless there is contamination by traumatic tap. 6) Few macrophages may be seen in normal CSF,[sic] and are increased following subarachnoid hemorrhage. 7) Both

	normal and abnormal CSFs may contain cells from the lining of the ventricles, choroids plexus, and ependymal cells. Cells seen in CSF ... Type of Cells Lymphocytes Neutrophils Eosinophil Basophil Monocyte Macrophage Ependymal (Unique to CSF) Blasts Malignant Cells" The laboratory's policy failed to define the staining characteristics for the body fluid Cytospin smears. 2. Review of the Wright Stain package insert stated: "EXPECTED RESULTS: The reaction of the cytoplasm to neutral staining is subject to many variables. The variable of the greatest magnitude is the resultant pH of the stain-buffer mixture at the cellular surfaces. The overall color of the red blood cells is a guide to stain quality and should be used in adjusting staining and buffering times for desired results. RBC'S: Pink-tan color. WBC'S: Nuclei with bright, bluish-purple chromatin light blue nucleoli. LYMPHOCYTES: Clear blue cytoplasm, red-purple granules may be present. Acidic stain yields pale blue cytoplasm, whereas alkaline stain yields gray or lavender lymphocyte cytoplasm. MONOCYTES: Bluish grey cytoplasm, azure granules usually present. NEUTROPHILS: Light purplish-pinkish or lavender granules in cytoplasm. Acidic stain yields pale neutrophilic granules, whereas a basic stain yields dark, prominent neutrophilic granules. EOSINOPHILS: Bright red or reddish-orange granules in cytoplasm. Acidic stain yields brilliant and distinct red granules, whereas basic stain yields deep gray or blue eosinophilic granules. BASOPHILS: Deep purple and violet-black granules in cytoplasm. PLATELETS: Red-purple granules in light blue cytoplasm." 3. The laboratory was asked on 02/05/2025 at 1:38 p.m. for documentation of stain QC for body fluid Cytospin smears performed in 2023 and 2024. No documentation of QC records was provided. The laboratory failed to document the staining characteristics for body fluid Cytospin smears. 4. A review of patient records revealed the following patients were tested and reported when no stain QC was performed: 02/20/2023 Patient M/R#: 029383 06/20/2023 Patient M/R#: 045788 06/27/2024 Patient M/R#: 037979 07/18/2024 Patient M/R#: 046650 07/24 /2024 Patient M/R#: 008233 09/11/2024 Patient M/R#: 15483 09/22/2024 Patient M /R#: 047927 11/01/2024 Patient M/R#: 022855 11/04/2024 Patient M/R#: 022850 5. During an interview on 02/55/2025 at 1:38 p.m., the Technical Consultant-2 confirmed the laboratory failed document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for body fluid Cytospin smears. Word Key: CSF- cerebral spinal fluid WBC- white blood cell RBC- red blood cell M/R#- medical record number