Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0999165	02/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pineville Childrens Clinic	101 Medical Park Blvd Suite A, Pineville, LA	

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	A Validation Survey was conducted February 17, 2025 at Pineville Children's Clinic - CLIA ID # 19D0461054. Pineville Children's Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to label in-use Complete Blood Count (CBC) quality controls with an open and expiration date as required by the manufacturer. Refer to D5415. 2. The laboratory failed to ensure supplies did not exceed their expiration dates for two (2) of three (3) rooms reviewed. Refer to D5417. 3. The laboratory failed to take corrective action when the room temperature exceeded the acceptable range for twenty (20) of two hundred seventy two (272) days reviewed. Refer to D5785 I. 4. The laboratory failed to take corrective actions when the freezer temperatures were not maintained within the acceptable range for one hundred ninety one (191) of two hundred seventy two (272) days reviewed. Refer to D5785 II. 5. The laboratory failed

	to take corrective actions when the refrigerator temperatures were not maintained within the acceptable range for seventy seven (77) of two hundred seventy two (272) days reviewed. Refer to D5785 III.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a written procedure for the establishment or verification of each new lot of hematology quality controls. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a written policy for hematology quality control (QC) new lot verification or establishment. 2. In interview on February 12, 2025 at 10:10 am, Testing Personnel 1 stated the policy is to run the new lot of QC five (5) times parallel with the old lot of quality control (QC) prior to putting into use. Testing Personnel confirmed that there was not a policy for new lot hematology QC verification in the policy and procedure manual.
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 observation by surveyor, review of manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to label in-use Complete Blood Count (CBC) quality controls with an open and expiration date as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on February 12, 2025 at 10:50 am revealed the laboratory utilizes the Sysmex XP-300 hematology analyzer with the Sysmex Eightcheck 3WP X-TRA quality controls for Complete Blood Count (CBC) testing. 2. Review of the Sysmex Eightcheck - 3WP X-TRA hematology control package insert under "Storage and shelf life after first opening" revealed "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 degrees celsius after being recapped". 3. Futher observation during the laboratory tour on February 12, 2025 at 10:50 am revealed the following Sysmex Eightcheck 3WP X-TRA quality controls in the refrigerator without an open and/or expiration date as required by the manufacturer: a) Low Abnormal - Lot 50210710 Expiration 04/30/2025 b) Normal - Lot 50210711 Expiration 04/30/2025 c) High Abnormal - Lot 50210712 Expiration 04

	/30/2025 4. In interview on February 12, 2025 at 11:00 am, Testing Personnel 1 confirmed the in use hematology controls were not labeled with an open and/or expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) 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. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration dates in two (2) of three (3) rooms where testing is routinely performed. Findings: 1. Observation by surveyor during the laboratory tour on February 12, 2025 at 11:21 am revealed the following expired supplies in various cabinets in two (2) of three (3) testing rooms: a) Urine CCM Vacuette, Lot A23093QV, Expiration date: 01/10/2025, Quantity: four (4) vacuettes b) eSwab Collection & Preservation of aerobic, anaerobic and fastidious bacteria, Lot 231079800, Expiration date 10/27/2024, Quantity: fourteen (14) swabs c) eSwab Collection & Preservation of aerobic, anaerobic and fastidious bacteria, Lot 230302400, Expiration date 06/08/2024, Quantity: thirty (30) swabs d) eSwab Collection & Preservation of aerobic, anaerobic and fastidious bacteria, Lot N30461600, Expiration date 01/30/2025, Quantity: nine (9) swabs e) Puritan Opti-swab liquid Amies Collection & Transport for viruses, chlamydiae, Mycoplasmas, and Ureaplasmas, Lot 230407, Expiration date 10/07/2024, Quantity eighteen (18) swabs f) BD Universal Viral Transport for Viruses, Chlamydiae, Mycoplasmas, and Ureaplasmas, Lot N30111500, Expiration date 08/14/2024, Quantity: seventeen (17) swabs g) BD Universal Viral Transport for Viruses, Chlamydiae, Mycoplasmas, and Ureaplasmas, Lot N30112700, Expiration date 08/20/2024, Quantity: two (2) swabs 2. In interview on February 12, 2025 at 11:30 am, Testing Personnel 1 confirmed the identified supplies were expired.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, temperature records and interview with personnel, the laboratory failed to take corrective action when the room temperature exceeded the acceptable range for twenty (20) of two hundred seventy two (272) days reviewed. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy to address the corrective actions when temperatures exceed the acceptable ranges. 2. Review of the laboratory's temperature logs from January 2024 through January 2025 revealed the acceptable range for room temperature as 68 - 87.8 degrees fahrenheit (20 - 31 degrees celsius). 3. Further review of the laboratory's temperature logs revealed the room temperature was documented as outside the acceptable limits without corrective actions for the following twenty (20) of two hundred seventy two (272) days reviewed: a) January 4,

2024: documented room temperature of 63.5 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) b) February 1, 2024: documented room temperature of 63 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) c) February 5, 2024: documented room temperature of 66 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) d) February 6, 2024: documented room temperature of 65 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) e) February 7, 2024: documented room temperature of 65 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) f) March 5, 2024: documented room temperature of 64.7 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) g) March 19, 2024: documented room temperature of 65.2 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) h) March 20, 2024: documented room temperature of 65.9 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) i) April 8, 2024: documented room temperature of 59 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) j) April 9, 2024: documented room temperature of 56 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) k) April 10, 2024: documented room temperature of 57 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) l) December 2, 2024: documented room temperature of 62.5 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) m) December 10, 2024: documented room temperature of 60.1 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) n) December 11, 2024: documented room temperature of 61.2 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) o) December 24, 2024: documented room temperature of 61.0 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) p) December 26, 2024: documented room temperature of 60.0 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) q) January 2, 2025: documented room temperature of 65.9 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) r) January 6, 2025: documented room temperature of 65.2 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) s) January 22, 2025: documented room temperature of 67.9 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) t) January 23, 2025: documented room temperature of 67.5 degree fahrenheit (acceptable range of 68-87.8 degree fahrenheit) 4. In interview on February 12, 2025 at 10:48 am, Testing Personnel 1 confirmed the laboratory did not have corrective actions for unacceptable room temperatures for the identified days. II. Based on review of laboratory policy, temperature records and interview with personnel, the laboratory failed to take corrective actions when the freezer temperatures were not maintained within the acceptable range for one hundred ninety one (191) of two hundred seventy two (272) days reviewed. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy to address the corrective actions when temperatures exceed the acceptable ranges. 2. Review of the laboratory's temperature logs from January 2024 through January 2025 revealed the acceptable range for the freezer as -5 to 5 degrees fahrenheit (-20 to -15 degrees celsius). 3. Further review of the laboratory's temperature logs revealed the freezer temperatures were documented as outside the acceptable limits without corrective actions for the following one hundred ninety one (191) of two hundred seventy two (272) days reviewed: a) January 17, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) b) January 29, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) c) January 30, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) d) February 1, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) e) February 6, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) f) February 20, 2024: documented freezer temperature of -8 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) g) February 21, 2024:

documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) h) February 23, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) i) March 4, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) j) March 6, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) k) March 8, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) l) March 20, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) m) April 5, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) n) April 8, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) o) April 9, 2024: documented freezer temperature of -7 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) p) April 10, 2024: documented freezer temperature of -8 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) q) April 12, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) r) April 17, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) s) April 23, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) t) April 24, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) u) April 25, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) v) April 29, 2024: documented freezer temperature of -8 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) w) April 30, 2024: documented freezer temperature of -7 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) x) May 1, 2024: documented freezer temperature of -10 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) y) May 2, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) z) May 3, 2024: documented freezer temperature of -8 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) aa) May 6, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) bb) May 7, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) cc) May 8, 2024: documented freezer temperature of -12 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) dd) May 9, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) ee) May 10, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) ff) May 13, 2024: documented freezer temperature of -10 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) gg) May 14, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) hh) May 15, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) ii) May 16, 2024: documented freezer temperature of -7 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) jj) May 17, 2024: documented freezer temperature of -7 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) kk) May 21, 2024: documented freezer temperature of -9 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) ll) May 23, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) mm) May 28, 2024: documented freezer temperature of -8 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) nn) May 29, 2024: documented freezer temperature of -6 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) oo) May 31, 2024: documented freezer temperature of -8 degree fahrenheit (acceptable range of -5 to 5 degree fahrenheit) pp) June 5, 2024: documented freezer temperature of -7 degree fahrenheit (acceptable range of -5 to 5

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D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

	(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. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to establish a written procedure for the establishment or verification of each new lot of hematology quality controls. Refer to D5401. 2. The laboratory failed to label in-use Complete Blood Count (CBC) quality controls with an open and expiration date as required by the manufacturer. Refer to D5415. 3. The laboratory failed to ensure supplies did not exceed their expiration dates for two (2) of three (3) rooms reviewed. Refer to D5417. 4. The laboratory failed to take corrective action when the room temperature exceeded the acceptable range for twenty (20) of two hundred seventy two (272) days reviewed. Refer to D5785 I. 5. The laboratory failed to take corrective actions when the freezer temperatures were not maintained within the acceptable range for one hundred ninety one (191) of two hundred seventy two (272) days reviewed. Refer to D5785 II. 6. The laboratory failed to take corrective actions when the refrigerator temperatures were not maintained within the acceptable range for seventy seven (77) of two hundred seventy two (272) days reviewed. Refer to D5785 III.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality assessment program was maintained to assure the quality of laboratory testing and identify failures as they occur. Refer to D6020. 3. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policy occurred. Refer to D6024. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to label in-use Complete Blood Count (CBC) quality controls with an open and expiration date as required by the manufacturer. Refer to D5415. 2. The laboratory failed to ensure supplies did not exceed their expiration dates for two (2) of three (3) rooms reviewed. Refer to D5417.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure that a quality assessment program was maintained to assure the quality of laboratory testing and identify failures as they occur. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policy occurred. Findings: 1. The laboratory failed to take corrective action when the room temperature exceeded the acceptable range for twenty (20) of two hundred seventy two (272) days reviewed. Refer to D5785 I. 2. The laboratory failed to take corrective actions when the freezer temperatures were not maintained within the acceptable range for one hundred ninety one (191) of two hundred seventy two (272) days reviewed. Refer to D5785 II. 3. The laboratory failed to take corrective actions when the refrigerator temperatures were not maintained within the acceptable range for seventy seven (77) of two hundred seventy two (272) days reviewed. Refer to D5785 III.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.