Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1074426	**(X3) Date Survey Completed** 11/25/2025
Name of Provider or Supplier Childrens Medical Association	**Street Address, City, State** 5697 Coral Ridge Dr, Coral Springs, FL	

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	An announced CLIA validation survey was conducted at CHILDRENS MEDICAL ASSOCIATION - CORAL SPRINGS OFFICE LAB from November 18, 2025 to November 25, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to keep records of the testing of Proficiency Testing (PT) in the Specialty of Hematology for three out of five events reviewed. Findings included: 1-Review of American Proficiency Institute (API) PT records for Hematology and Microbiology (1st , 2nd and 3rd third event of 2024 and first and second event of 2025), revealed that the laboratory did not maintain instrument testing records of the Horiba ABX Micros 60 and Throat Culture Log (TCL) for PT samples as follows: a) 1st event 2024: No analyzer results and no TCL record. b) 2nd event 2024: No analyzer results and no TCL record. c) 3rd event 2024: No analyzer results and no TCL record. 2-During an interview on 11/18/2025 at 12:30 PM, Testing Personnel #1 confirmed that the laboratory failed to have the records for PT listed above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to follow manufacturer Instructions for Use (IFU) for the Selective Strep Agar, for incubation temperature in the throat culture for two out of two years reviewed (2024-2025). Findings included: 1-During the laboratory tour on 11/18/2025 at 10:00 AM, the surveyor observed that the laboratory was using the Hardy Diagnostic Selective Strep Agar with Lot number 669069 for the Throat Culture. 2- Review of the Hardy Diagnostic Selective Strep Agar IFU, in section "Procedure", revealed that stated, "Incubate at 35C for 18-24 hours." 3-Review of the Procedure Manual signed by the Laboratory Director on 01/13/2025, revealed that the policy "Quality Control Procedures of Throat Culture", showed instruction to incubate the culture plate at 35-37 Degrees Celsius (C). 4-Review of the temperature log revealed that the laboratory had an acceptable temperature range of 34-38 for the incubator. 5-Review of Incubator temperature records for 2024 and 2025, revealed the following: a)On 06/27/2024, 06/24/2025, 06/29/2025, 08/21/2025, 08/28/2025, 11/11/2025; the recorded temperature was 39C, outside of the established range and the manufacturer range. b) On 08/08/2025 and 08/24/2025; the recorded temperature was 40C, outside of the established temperature and the manufacturer range. c)The remaining days for this period the temperatures ranged between 37 to 38C, outside of the manufacturer's 6-Based on review of the FORM CMS-116, signed by the Laboratory Director on 10/21/2025, the laboratory had an annual volume of Throat Culture of 1,967.00 cases. 7-During an interview on 11/18/2025 at 11/45 AM, Testing personnel # 1 acknowledged that the laboratory failed to follow the IFU for the incubation temperature of the Hardy Diagnostic Selective Strep Agar for the years of 2024 and 2025.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory report failed to list the complete laboratory name in the final report or patient chart report from 03/04/2024 to 11/18/2025. Findings Included: 1-Review of 5 patient reports for Complete Blood Cell Count (CBC) in the following dates: Patient #1 (P#1) (03/04/2024), P#2 (09/19/2024), P#3 (04/07/2025) P#4 (10/13/2025) and P#5 (11/18/2025), revealed that the reports for failed to include the compete laboratory name 2-Review of patient chart

	for result of Throat culture on 03/05/2024, 09/19/2024, 04/11/2025 and 10/15/2025; revealed that the charts failed to list the complete name for the laboratory. 3-During an interview on 11/18/2025 at 10:30 AM, the Testing Personnel #1 confirmed that the reports of the laboratory failed to include the complete name of the laboratory that performed the CBC test and throat culture.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of patient testing during competency evaluation for testing personnel (TP) for 11 out 11 in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 10/21/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Consultant (TC) for Hematology and Microbiology specialties. The laboratory had eleven testing personnel (TP1, TP2, TP3, TP4, TP5, TP6, TP7, TP8, TP9, TP10 and TP11. 2- Review of annual competency assessment checklist for TP1 on 8/1/2025 revealed that direct observation of patient testing was observed and signed by TP4, who had no delegation letter to do competency. 3- Review of competency assessments checklists for TP2 (04/14/2025), TP3 (08/27/2025, TP4 (09 /16/2025), TP5 (09/15/2025), TP6 (09/03/2025), TP7 (01/03/2025), TP8 (02/10 /2025), and TP9 (08/25/2025) revealed that direct observation of patient testing were observed and signed by TP1. 4- Review of training checklist for TP10 (06/06/2025) and TP11 (9/22/2025) for Hematology and Microbiology specialties, were signed by TP1 and TP4. The laboratory did not provide an initial competency assessment for direct observation of patient testing signed by the TC. 5-The laboratory did not provide competency assessment for direct observation of patient testing signed by the TC. 6- During interview on 11/18/2025 at approximately 1:400 AM, the lead TP1 confirmed that the TC did not perform direct observation of patient testing competency for all staff in the laboratory from January through September of 2025.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of performance of instrument and function check of the HORIBA Hematology analyzer during competency evaluation for testing personnel (TP) for 11 out 11 in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 10/21/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC) and Technical Consultant (TC) for Hematology and Microbiology specialties. The laboratory had eleven testing personnel (TP1, TP2, TP3, TP4, TP5, TP6, TP7, TP8, TP9, TP10 and TP11. 2- Review of annual competency assessment checklist for TP1 on 8/1/2025 revealed that

	direct observation performance of instrument and function check for the HORIBA Hematology analyzer was observed and signed by TP4, who had no delegation letter to do competency. 3- Review of competency assessments checklists for TP2 (04/14 /2025), TP3 (08/27/2025, TP4 (09/16/2025), TP5 (09/15/2025), TP6 (09/03/2025), TP7 (01/03/2025), TP8 (02/10/2025), and TP9 (08/25/2025) revealed that direct observation for the performance of instrument and function check of the HORIBA Hematology analyzer were observed and signed by TP1. 4- Review of training checklist for TP10 (06/06/2025) and TP11 (9/22/2025) for Hematology specialty, were signed by TP1 and TP4. The laboratory did not provide an initial competency assessment for direct observation for the performance of instrument and function check of the HORIBA Hematology analyzer signed by the TC. 5-The laboratory did not provide competency assessment for direct observation for the performance of instrument and function check of the HORIBA Hematology analyzer signed by the TC. 6- During interview on 11/18/2025 at approximately 10:00 AM, the lead TP1 confirmed that the TC did not perform direct observation of patient testing competency for all staff in the laboratory from January through September of 2025.