Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2189959	06/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cook Children's Pediatrics Plano	4001 W 15th St Suite 350, Plano, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, direct observations, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for documenting the initial opening date for 1 of 1 HemoPoint H2 n x t Microcuvettes in June 2022. Findings: 1. Review of HemoPoint H2 n x t Microcuvettes package insert revealed: "Storage HemoPoint H2 n x t microcuvettes are to be stored solely in the original container and at room temperature 59-86F (15-30C). DO NOT refrigerate! Use cuvettes within 3 months after opening container. Document the initial opening date on the container

	label in the space provided." 2. During a tour of the laboratory on 06/28/2022 at 12:05 pm, the surveyor observed the following on the laboratory counter: 1 opened bottle of HemoPoint H2 n x t Microcuvettes; lot #2200968; expiration date: 03/31/2024 The bottle was NOT labeled with the open date as required by the manufacturer. 3. During an interview on 06/28/2022 at 12:05 pm, Testing Person-4 confirmed the bottle of microcuvettes was not labeled with the open date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, the laboratory's CMS 116 form, and confirmed in interview, the laboratory failed to perform verification studies for the Sysmex pocH-100i CBC (complete blood count) hematology analyzer prior to reporting 1176 of 1176 patient test results. Findings: 1. Review of the Sysmex pocH-100i Installation and Method Verification Manual revealed: "Section 4 Method Verification Protocols To verify that the analyzer meets manufacturer's performance claims, perform the following studies: Precision Calibration Verification Reportable Range Verification (Verification of Linearity Studies) Carryover Study It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation Studies and Reference Range Verification Typically, integration studies are performed on new analyzers to verify and document satisfactory performance according to the manufacturer's specifications. It is up to the laboratory to perform more extensive studies if they deem it necessary to satisfy requirements over and above what is contained in these protocols. Data summaries and raw data from these studies can be organized in this section of the binder for future reference." 2. Review of the laboratory's CMS 116 form submitted on the day of the survey revealed the Sysmex pocH-100i hematology analyzer was used to perform CBCs. Records further revealed the Sysmex pocH-100i analyzer was put in-use 08/2020. The laboratory was asked to provide verification studies on the Sysmex pocH-100i analyzer prior to reporting 1176 patient test results that included: a. Accuracy b. Precision c. Reportable range of test results for CBC analytes d. Verification of the Sysmex pocH-100i manufacturer's reference intervals for CBC analytes that were appropriate for the laboratory's population. e. Calibration verification (as required by the manufacturer) f. Carryover study (as required by the manufacturer) No verification studies were provided. 3. During an interview on 06/28/2022 at 9:32 am, Testing Person-4 confirmed no verification studies were performed prior to performing patient testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS (Center for Medicare & Medicaid Services) 209 form, personnel records, and interview with staff, the Technical Consultant (TC) failed to evaluate and document performance for 3 of 8 Testing Persons (TP-5, TP6, TP-8) responsible for moderate complexity testing at least semiannually during the first year that testing persons analyzed patient specimens. Findings included: 1. Review of the laboratory's policy titled " NON-WAIVED LABORATORY QUALITY ASSESSMENT PLAN" revealed: "POLICY... C. Technical Consultant The Technical Consultant is responsible for technical and scientific oversight. The Technical Consultant will meet all the qualifications listed under the Technical Consultant's Job Description (see attached)." Review of the "Technical Consultant Job Description" revealed: "The Technical Consultant is responsible for technical and scientific oversight. The Technical Consultant ... 8. Evaluates the competency of all testing personnel on an ongoing basis. 9. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodologies or instrument changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology of instrumentation." 2. Review of the submitted CMS 209 form revealed Testing Person-5 (TP-5), Testing Person-6 (TP-6) and Testing Person-8 (TP-8) were listed to perform moderate complexity testing. 3. Review of personnel records from 2020, 2021 and 2022 revealed the following: TP-5 Training documentation for "CBC": training date 12/11/2020 Semiannual Competency Assessments for "CBC": 04 /29/2021 & 07/09/2021 Evaluator: Signed by Testing Person-4 who was NOT listed on the CMS-209 as the Technical Consultant TP-6 Training documentation for "CBC": training date 12/11/2020 Semiannual Competency Assessment for "CBC": 07 /09/2021 Evaluator: Signed by Testing Person-4 who was NOT listed on the CMS-209 as the Technical Consultant TP-8 Training documentation for "CBC": training date 09/20/2021 Semiannual Competency Assessment for "CBC": 3/18/2022 Evaluator: Signed by Testing Person-4 who was NOT listed on the CMS-209 as the Technical Consultant The TC failed to evaluate and document performance at least semiannually during the first year of patient testing. 4. During an interview on 06/28 /2022 at 10:00 am, Testing Person-4 confirmed the above findings. Word key: CBC: complete blood count