Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2024578	06/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hopkins Minor Emergency Center Llc	106 Hodge St, Sulphur Springs, 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 out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
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 surveyor observation, review of laboratory documents, the Centers for Medicare and Medicaid Services (CMS) Form 116, and confirmed in an interview, the laboratory failed to follow the manufacturer's storage requirements to ensure a proper storage temperature of 2 - 8 degrees Celsius (C) for 67 of 111 days reviewed from November 2022 to March 2023. The findings included: 1. In a tour of the laboratory on 6/2/2023 at 12:30 hours, the surveyor observed the following waived testing items and their respective storage temperature in the laboratory refrigerator: 1 box Abbott Afinion HbA1c Controls, storage temperature 2 - 8 (degrees) C 1 box Quantimetrix Dipper Urinalysis Dipstick Control, storage temperature 2 - 8 (degrees) C 4 boxes Piccolo Lipid Panel, storage temperature of 2 - 8 (degrees) C 2 boxes Piccolo Comprehensive Metabolic Panel, storage temperature of 2 - 8 (degrees) C 2. Review of laboratory temperature records for November 2022 to March 2023 had the following 67 days with a documented temperature outside of the acceptable range of 2 - 8 (degrees) Celsius, or 35.6 - 46.4 (degrees) Fahrenheit (F) November 2022: 15 days 11/10/2022 - 26.1 (degrees) F 11/11/2022 - 28.1 (degrees) F 11/12/2022 - 52.8 (degrees) F 11/14/2022 - 52.8 (degrees) F 11/15/2022 - 52.8 (degrees) F 11/16/2022 - 52.8 (degrees) F 11/17/2022 - 52.8 (degrees) F 11/18/2022 - 52.8 (degrees) F 11/21 /2022 - 52.8 (degrees) F 11/23/2022 - 52.8 (degrees) F 11/24/2022 - 52.8 (degrees) F

	11/26/2022 - 52.8 (degrees) F 11/28/2022 - 52.8 (degrees) F 11/29/2022 - 52.8 (degrees) F 11/30/2022 - 52.8 (degrees) F December 2022: 22 days 12/2/2022 - 52.8 (degrees) F 12/3/2022- 52.8 (degrees) F 12/5/2022- 52.8 (degrees) F 12/6/2022- 52.8 (degrees) F 12/7/2022- 52.8 (degrees) F 12/8/2022- 52.8 (degrees) F 12/9/2022- 52.8 (degrees) F 12/10/2022- 52.8 (degrees) F 12/12/2022- 52.8 (degrees) F 12/13/2022- 52.8 (degrees) F 12/14/2022- 56.9 (degrees) F 12/15/2022- 52.8 (degrees) F 12/16 /2022- 52.8 (degrees) F 12/19/2022- 52.8 (degrees) F 12/20/2022- 52.8 (degrees) F 12 /21/2022- 52.8 (degrees) F 12/22/2022- 52.8 (degrees) F 12/23/2022- 52.8 (degrees) F 12/24/2022- 52.8 (degrees) F 12/25/2022- 52.8 (degrees) F 12/26/2022- 52.8 (degrees) F 12/29/2022- 52.8 (degrees) F January 2023: 24 days 01/01/2023 - 52.8 (degrees) F 01/02/2023 - 52.8 (degrees) F 01/03/2023 - 56.9 (degrees) F 01/04/2023 - 68.7 (degrees) F 01/05/2023 - 56.9 (degrees) F 01/06/2023 - 67.6 (degrees) F 01/07 /2023 - 56.9 (degrees) F 01/08/2023 - 68.9 (degrees) F 01/10/2023 - 56.9 (degrees) F 01/12/2023 - 56.9 (degrees) F 01/13/2023 - 56.9 (degrees) F 01/16/2023 - 56.9 (degrees) F 01/17/2023- 56.9 (degrees) F 01/18/2023- 56.9 (degrees) F 01/19/2023- 56.9 (degrees) F 01/20/2023- 56.9 (degrees) F 01/21/2023- 56.9 (degrees) F 01/23 /2023- 56.9 (degrees) F 01/25/2023- 56.9 (degrees) F 01/26/2023- 56.9 (degrees) F 01 /27/2023- 56.9 (degrees) F 01/28/2023 - 62 (degrees) F 01/30/2023 - 56.9 (degrees) F 01/31/2023 - 56.9 (degrees) F February 2023: 6 days 2/3/2023 - 56.9 (degrees) F 2/4 /2023 - 56.9 (degrees) F 2/6/2023 - 56.9 (degrees) F 2/7/2023 - 57.6 (degrees) F 2/8 /2023 - 51.6 (degrees) F 2/9/2023 - 51 (degrees) F 3. Review of the CMS Form 116, section VI. "Waived Testing" had an estimated total annual test volume of 10,000. 4. In an interview on 6/2/2023 at 12:15 hours, in the breakroom, the technical consultant (TC 1) confirmed that the above-recorded temperatures were outside of the manufacturer's acceptable range.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, laboratory documents, the Centers for Medicare and Medicaid Services (CMS) Form 116, and confirmed in an interview, the laboratory failed to ensure a proper storage temperature for hematology quality control of 2 - 8 degrees Celsius (C) for 67 of 111 days reviewed from November 2022 to March 2023. The findings included: 1. In a tour of the laboratory on 6/2/2023 at 12:30 hours, the surveyor observed the following control items for the Sysmex PoChi-100 hematology analyzer and the documented storage temperature in the laboratory refrigerator: 1 box of Sysmex EightCheck 3WP X-TRA, storage temperature 2 - 8 (degrees) C, with 6 unopened control vials inside, and three opened control vials in the door of the refrigerator. 2. Review of laboratory temperature records for November 2022 to March 2023 had the following 67 days with a documented temperature outside of the acceptable range of 2 - 8 (degrees) Celsius, or 35.6 - 46.4 (degrees) Fahrenheit (F) November 2022: 15 days 11/10/2022 - 26.1 (degrees) F 11/11/2022 - 28.1 (degrees) F 11/12/2022 - 52.8 (degrees) F 11/14/2022 - 52.8 (degrees) F 11/15/2022 - 52.8

	(degrees) F 11/16/2022 - 52.8 (degrees) F 11/17/2022 - 52.8 (degrees) F 11/18/2022 - 52.8 (degrees) F 11/21/2022 - 52.8 (degrees) F 11/23/2022 - 52.8 (degrees) F 11/24 /2022 - 52.8 (degrees) F 11/26/2022 - 52.8 (degrees) F 11/28/2022 - 52.8 (degrees) F 11/29/2022 - 52.8 (degrees) F 11/30/2022 - 52.8 (degrees) F December 2022: 22 days 12/2/2022 - 52.8 (degrees) F 12/3/2022- 52.8 (degrees) F 12/5/2022- 52.8 (degrees) F 12/6/2022- 52.8 (degrees) F 12/7/2022- 52.8 (degrees) F 12/8/2022- 52.8 (degrees) F 12/9/2022- 52.8 (degrees) F 12/10/2022- 52.8 (degrees) F 12/12/2022- 52.8 (degrees) F 12/13/2022- 52.8 (degrees) F 12/14/2022- 56.9 (degrees) F 12/15/2022- 52.8 (degrees) F 12/16/2022- 52.8 (degrees) F 12/19/2022- 52.8 (degrees) F 12/20/2022- 52.8 (degrees) F 12/21/2022- 52.8 (degrees) F 12/22/2022- 52.8 (degrees) F 12/23 /2022- 52.8 (degrees) F 12/24/2022- 52.8 (degrees) F 12/25/2022- 52.8 (degrees) F 12 /26/2022- 52.8 (degrees) F 12/29/2022- 52.8 (degrees) F January 2023: 24 days 01/01 /2023 - 52.8 (degrees) F 01/02/2023 - 52.8 (degrees) F 01/03/2023 - 56.9 (degrees) F 01/04/2023 - 68.7 (degrees) F 01/05/2023 - 56.9 (degrees) F 01/06/2023 - 67.6 (degrees) F 01/07/2023 - 56.9 (degrees) F 01/08/2023 - 68.9 (degrees) F 01/10/2023 - 56.9 (degrees) F 01/12/2023 - 56.9 (degrees) F 01/13/2023 - 56.9 (degrees) F 01/16 /2023 - 56.9 (degrees) F 01/17/2023- 56.9 (degrees) F 01/18/2023- 56.9 (degrees) F 01 /19/2023- 56.9 (degrees) F 01/20/2023- 56.9 (degrees) F 01/21/2023- 56.9 (degrees) F 01/23/2023- 56.9 (degrees) F 01/25/2023- 56.9 (degrees) F 01/26/2023- 56.9 (degrees) F 01/27/2023- 56.9 (degrees) F 01/28/2023 - 62 (degrees) F 01/30/2023 - 56.9 (degrees) F 01/31/2023 - 56.9 (degrees) F February 2023: 6 days 2/3/2023 - 56.9 (degrees) F 2/4/2023 - 56.9 (degrees) F 2/6/2023 - 56.9 (degrees) F 2/7/2023 - 57.6 (degrees) F 2/8/2023 - 51.6 (degrees) F 3. Review of the CMS Form 116, section VII. "Non-Waived Testing" had an estimated total annual test volume of 14,000 for the specialty of hematology. 4. In an interview on 6/2/2023 at 12:15 hours, in the breakroom, the technical consultant (TC 1) confirmed that the above temperatures recorded were outside of the manufacturer's acceptable range for the Sysmex EightCheck 3WP X-TRA hematology controls.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, reagent instructions for use, and confirmed in interview, the laboratory failed to record the in use, or open date, for 3 of 3 controls in use for the Sysmex poc100i hematology analyzer observed on 6/2/2023. The findings included: 1. In a tour of the laboratory on 6/2/2023 at 12:30 hours, the surveyor observed the following hematology control vials in a cup secured in the refrigerator door without indication of when it was put into use: EightCheck 3WP X-TRA Abnormal Low Control: Lot 30810710, Exp: 2023-06-26 EightCheck 3WP X-TRA Normal Control: Lot 30810711, Exp 2023-06-28 EightCheck 3WP X-TRA Abnormal High Control: Lot 30810712, Exp 2023-06-28 In an interview at 12:33 hours, in the laboratory, testing person (TP) 6 stated that the QC was put into use "...more than likely the last week of May." 2. Review of the "Sysmex EIGHTCHECK -3WP X-TRA" instructions for use, section "Storage and shelf life after first opening" had the following statement: "Opened and recapped vials and vials whose caps have been

	pierced will retain stability for 14 days if stored at 2-8 (degrees) C after being re-capped. 3. In an interview on 6/2/2023 at 12:40, in the breakroom, the technical consultant (TC 1) confirmed that the controls in use for the Sysmex pocH-100i did not have an open, or in-use date, documented on the vials.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of laboratory documents, laboratory control records, laboratory patient records, and confirmed in an interview, the laboratory failed to document quality controls (QC) on days where patients were tested on the Sysmex pocH-100i hematology analyzer for 2 of 44 days reviewed in November and December 2022. The findings included: 1. Review of a laboratory quick sheet posted in the laboratory on the laboratory refrigerator had the following "Daily Lab Duties: "CBC Controls" 2. Review of QC records had the following 2 days where QC was not documented on days where patient testing performed on the Sysmex pocH-100i: November 19, 2022 - no documented QC 3 patients tested on 11/19/2022 (see patient list) November 28, 2022 - no documented QC 1 patient tested on 11/28/2022 (see patient list) 3. In an interview on 6/2/2023 at 13:05, in the breakroom, the technical consultant (TC 1) confirmed that the laboratory did not have documentation of QC being performed on the above days when patient testing was performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assurance (QA) policy, QA checklists, QC records, patient records, and confirmed in an interview, the laboratory failed to have an effective QA system in place to monitor and identify issues in the analytic system for four of six reviews performed from 2022 to 2023. The findings included: 1. Review of the laboratory policy titled "Quality Assurance Policies and Procedures", section A "POLICIES AND PROCEDURES" had the following statement: "The laboratory has established a Quality Assurance (QA) program. This is the policy of this laboratory to apply the principles of this QA program to all activities of this laboratory, including preanalytic, analytic and postanalytic activities. The QA program assures that accurate, reliable, and prompt reporting of test results and provides methods to evaluate the effectiveness of its policies and procedures, to identify and correct problems, and assure the adequacy and competency of the staff. The laboratory will use a checklist system to provide periodic monitoring of the

	quality assurance indicators. If no problems are identified, monitoring will be stopped. It is not the purpose of this QA program to continuously monitor indicators which are working correctly. However, if problems occur, monitoring will be reinstated until the problems are identified and corrected." 2. Review of the laboratory "Quality Assurance Checklist" had the following items to be checked: "Quality Control Policies Were Performed: ___ All required temperatures were recorded daily and within range. ___ All instrument maintenance was performed and documented. ___ Remedial action performed was documented and reviewed. ___ Daily controls were performed and within acceptable limits before patient testing. ___ Mean values/SD's for controls reflect the laboratory values. Adjusted ___ calibrations are current and within acceptable time frames. Last___Next___ ___ QC action log completed. Patient reviews completed if two controls were out of range. 3. A review of laboratory documents, laboratory control records, laboratory patient testing, and confirmed in an interview, the QA program failed to monitor and identify remediate patients tested on the Sysmex pocH-100i where no quality controls (QC) were documented for 2 of 44 days reviewed in November and December 2022. Refer to D5447 4. In surveyor observation, laboratory documents, the Centers for Medicare and Medicaid Services (CMS) Form 116, and confirmed in an interview, the QA program failed to identify and document corrective actions for the improper storage of hematology quality controls for 67 of 111 days reviewed from November 2022 to March 2023. Refer to D5413. 5. Based on surveyor observation, reagent instructions for use, and confirmed in interview, the laboratory failed to record the in-use, or open date, for 3 of 3 controls in use for the Sysmex poc100i hematology analyzer observed on 6/2/2023. Refer D5415. 6. Review of the completed "Quality Assurance Checklists" included documented activities (check marks) that indicated a review and the subsequent acceptability of all the QA items listed including that daily controls were performed and within acceptable limits before patient testing and acceptable temperature requirements were documented for the following months as of the indicated signature date: November 2022 - Signed by the LD on 12/1/2022 December 2022 - Signed by the LD on 12/27/2022 January 2023 - Signed by the LD on 1/30/2023 March & April 2023 - Evaluated by TC 1 and signed by the laboratory director (LD) on 6/11/2023 May 2023 - Evaluated by the technical consultant (TC 1) and signed by the LD on 6/2 /2023. 7. In the exit interview at 14:00 hours, in the breakroom, it was acknowledged by the technical consultant (TC 1) that the QA policy and checklist in place was not effective in monitoring and identifying problems throughout the analytic portion of the laboratory from November 2022 to May 2023.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assurance (QA) policy, QA documentation, laboratory record review, laboratory personnel record review, and confirmed in interviews, the laboratory director failed to have a QA program in place to maintain the quality of laboratory services from the general laboratory system to

	the analytic laboratory system for four of six months reviewed from 2022 to 2023. Refer to D5791.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicaid and Medicare Services (CMS) personnel form 209, operator's instructions for use, laboratory documents, and confirmed in an interview, the laboratory failed to ensure that training was documented on the Sysmex pocH-100i hematology analyzer for three of nine personnel, qualified under CFR 493.1423(b)(4) before performing moderate complexity testing in 2022 and 2023. Refer to D6066
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicaid and Medicare Services (CMS) personnel form 209, operator's instructions for use, laboratory documents, and confirmed in interview, the laboratory failed to document training for the Sysmex pocH-100i hematology analyzer for three of nine personnel performing moderate complexity testing in 2022 and 2023. The findings included: 1. Review of the CMS personnel form 209 had the following three testing personnel (TP) qualifying under CFR 493.1423 (b)(4) TP 2 - hired April 2023 TP 6 - hired May 2022 TP 7 - hired September 2022 2. Review of the Sysmex pocH-100i hematology analyzer instructions for use, chapter 2 "Safety Information", subsection 2.12 "Personnel" had the following statements: "Personnel using this instrument must read the Instructions for Use thoroughly beforehand, and must operate the instrument correctly." Surveyor queried for training documentation for TP 2, TP 6, and TP 7 and none was provided. 3. In an interview on 6/2/2023 at 11:25 hours, in the breakroom, the technical consultant (TC 1) and TP 1 stated that training specific to the Sysmex pocH-100i hematology analyzer had not been documented for the above testing personnel prior to being released for patient testing.