Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2024578	06/26/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on review of 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) documentation and staff interview, the laboratory director failed to provide the required signatures attesting to the routine integration of samples into the patient workload using the laboratory's routine methods. Findings: 1. Review of API PT attestation forms for hematology testing in the 3rd event 2017 and 1st event 2018 showed that testing person 1 (TP1-CMS form 209) had signed as lab director designee. The laboratory director (CMS form 209) had not signed the forms. 2. Review of lab testing personnel records revealed that TP 1 did not meet the education and training requirements for laboratory director or for delegation of signatory authority as technical consultant. 3. In an interview at the site on 06-26-2019, TP 1 stated she was not aware of the regulatory requirements regarding the signing of PT attestation statements. .
D5805	TEST REPORT CFR(s): 493.1291(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 review of patient reports for hematology testing, confirmed by staff interview, the laboratory failed to include positive patient identification and the physical location of the laboratory in test reports. Findings: 1. Copies of patient reports were reviewed. Hematology testing results were found to be identified by the patient's first and last name only. No information on the name or address of the testing location were included in the report. 2. In an interview at the site on 06-26-2019, TP 1 confirmed that the forms reviewed were representative of the patient reports for hematology testing in use at the facility. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on review of laboratory competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant (TC-CMS form 209) failed to evaluate the competency of testing personnel using the required criteria. Findings: 1. Personnel competency verification documents were reviewed. Forms dated 2017, 2018 and 2019, signed by the LD were found. On each was the phrase, "The above employee has been deemed competent in all aspects of the lab environment. The individual will be evaluated annually." No mention of the methods or criteria of evaluation were included. No documentation dated 2018 was found for TP 2 or TP 3. 2. In an interview at the site on 06-26-2019, TP1 confirmed that the forms reviewed served as competency verification for all testing personnel.