Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406206	07/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Joseph's Health	600 Pleasant Ave, Park Rapids, MN	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of a non-regulated Hematology analyte at least twice annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02/19 at 8:25 a.m. 2. The Fern Test microscopic examination procedure was included in the Laboratory Policy Manual.. 3. Twice annual Fern Testing verification of accuracy records were not found for 2017 or 2018. The laboratory was unable to provide documentation of verifications upon request. 4. In an interview on 07/02/19 at 4:00 p.m., the GS confirmed the accuracy of the Fern Test microscopic examination had not been verified twice annually in 2017 and 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate Chemistry and Hematology reference intervals (normal values) in the procedure manual (10). Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02/19 at 8:25 a.m. A. Chemistry 1. A Radiometer ABL 800 chemistry analyzer was observed as present and available for use during the tour. The GS indicated blood gas testing was performed on the analyzer. 2. The normal values found in the Arterial Blood Gas Normals list, found in the ABG's and ABL 800 Procedure Manual, for the analytes below were discrepant with those indicated on the patient test report reviewed on date of survey. See below. Test List Report pH 7.340-7.440 7.350-7.450 pCO2 35-45 35.0-42.0 TCO2 23-27 21.0-25.0 3. In an interview on 07/03/19 at 11:40 a.m., the GS confirmed the normal value discrepancies between the Arterial Blood Gas test report and the list. B. Hematology 1. A Sysmex XT-2000i hematology analyzer and a Streck ESR Auto-Plus analyzer were observed as present and available for use during the tour. The GS indicated Complete Blood Count testing was performed on the Sysmex XT-2000i and Erythrocyte Sedimentation Rate (ESR) testing was performed on the Streck ESR Auto-Plus. 2. The Hemoglobin (HGB) normal value found on the Hematology manual result form was discrepant with that indicated on patient test report reviewed on date of survey. See below. Test Form Report HGB 13.9-16.3 12.0-15.0 3. The female patient ESR normal value found on the Hematology manual result form was discrepant with that indicated on patient test report reviewed on date of survey. See below. Test Form Report ESR 0-20 0-25 4. In an interview on 07/03/19 at 9:45 a.m. and 10:00 a.m. respectively, the GS confirmed the HGB and ESR normal value discrepancy between the test reports and the manual result form.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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, document review, and interview with laboratory personnel, the laboratory failed to ensure a solution used for Microbiology microscopic examinations was not used after the expiration date, potentially affecting 1 patient test result. Findings are as follows: 1. The laboratory performed Microbiology testing as as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02 /19 at 8:25 a.m. 2. A secondary container with expired Gram Iodine stain was observed in use and the expired stock bottle was observed in a flammable materials

	storage cabinet during the tour. See below. Stain Lot Exp. date BD Gram Iodine 8143565 6/30/19 3. A Gram Stain using the expired Gram Iodine was performed on one patient specimen on 07/01/19 per laboratory records. 4. In an interview on 07/02 /19 at 9:00 a.m., the GS confirmed the Gram Iodine stain was in use and had expired.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform calibration verification on a Chemistry analyzer and two Hematology analyzers at least once every 6 months (180 days). Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02/19 at 8:25 a. m. A. Chemistry 1. A Radiometer ABL 800 chemistry analyzer was observed as present and available for use during the tour. The GS indicated blood gas testing was performed on the analyzer. 2. Calibration verification was required every six months as indicated in the ABG's and ABL 800 Procedure Manual. 3. The laboratory exceeded the six month calibration verification interval on one occasion in the time period reviewed, January 2017 to April 2019. See below Calibration verification dates Previous Subsequent Time elapsed 02/08/17 01/19/18 345 days The laboratory was unable to provide additional calibration verification records for 2017 upon request. 4. In an interview on 07/03/19 at 11:40 a.m., the GS confirmed the above finding. B. Hematology 1. A Siemens CA-1500 analyzer and a Quidel Triage analyzer were observed as present and available for use during the tour. The GS indicated Fibrinogen testing was performed on the CA-1500 and D-Dimer testing was performed on the Triage.. 2. CA-1500 calibration verification was required every six months as indicated in the Fibrinogen Sysmex CA 1500 Coagulation Analyzer procedure located in the Coagulation Procedure Manual. 3. The laboratory exceeded the CA-1500 six month calibration verification interval on two occasions in the time period reviewed, January 2017 to April 2019. See below Calibration verification dates Previous Subsequent Time elapsed 05/09/17 12/28/17 233 days 12/28/17 08/01/18

	216 days The laboratory was unable to provide additional CA-1500 calibration verification records for 2017 or 2018 upon request. 4. Triage calibration verification was required every six months as indicated in the Triage D-Dimer Test procedure located in the Coagulation Procedure Manual. 5. The laboratory exceeded the Triage six month calibration verification interval on one occasion in the time period reviewed, January 2017 to April 2019. See below Calibration verification dates Previous Subsequent Time elapsed 11/16/17 08/29/18 286 days The laboratory was unable to provide additional Triage calibration verification records for 2018 upon request. 6. In an interview on 07/03/19 at 10:45 and 11:00 a.m. respectively, the GS confirmed the above finding.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory's Individualized Quality Control Plans (IQCP's) did not adequately define the type and /or frequency of required quality control testing. Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02/19 at 8:25 a.m. 2. IQCP's developed for the tests listed below did not adequately define the type and frequency of required quality control testing. Illumigene C. diff BactiStaph Cefinase Disc Exempt Media PYR Vitek 2 IID cards 3. IQCP's developed for the tests listed below did not adequately define the type of required quality control testing. Triage D-Dimer hCG Combo Rapid Test Amnisure ROM Amniotest iSTAT Troponin iSTAT EG7+ Immunocard STAT EHEC 4. In an interview on 07/02/19 at 9:35 a.m., the GS confirmed the above finding.
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 document review and interview with laboratory personnel, the laboratory

	failed to ensure the final test result date was indicated on the test report (c)(3). Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02/19 at 8:25 a. m. 2. Patient test result reports reviewed on date of survey did not indicate the final test result date. 3. In an interview at 9:20 a.m., the GS confirmed the final test result date was not included on the test reports.
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 document review and interview with laboratory personnel, the technical consultant (TC) failed to include all required elements in the a microscopic examination competency assessment for three of three testing personnel in 2017 and 2018. The competency assessment required elements found at 493.1413(b)(8) are listed below. 1) Direct observation of routine test performance 2) Monitoring the recording and reporting of test results 3) Review of test records 4) Direct observation of instrument maintenance 5) Assessment of test performance using blind samples 6) Assessment of problem solving skills Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/02/19 at 8:25 a.m. 2. The Fern Test microscopic examination procedure was included in the Laboratory Policy Manual.. 3. Three medical providers performed Fern Test microscopic examinations in 2017 and 2018 as indicated by the General Supervisor (GS) during a discussion on 07/02/19 at 4:00 p. m. 4. The GS indicated the Fern Test competency assessment included an image review and a quiz. The laboratory was unable to provide additional documentation for the remaining required competency assessment elements upon request. 5. In an interview at 4:00 p.m. on 07/02/19, the GS confirmed the three providers were not fully assessed for Fern Test competency in 2017 and 2018