Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1069567	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier Memorial Hospital Of South Bend/Main Lab	**Street Address, City, State** 615 N Michigan Street, South Bend, IN	

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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory failed to have a test request from an authorized person for a Trichomonas vaginalis antigen test by EIA (enzyme immunosorbent assay) for one of three patient records (Patient #1) reviewed who received wet mount testing. Findings included: 1. Review of patient records indicated the following: a. Wet mount testing was performed for Patient #1 (12-9-2018 at 5:38 PM); Patient #2 (12-9-2018 at 12:18 AM); and Patient #5 (2-2-2019 at 6: 29 AM). b. The wet mount test results were positive for Patient #1 (1+) and Patient #2 (2+). c. Patient #1 was the only patient that had a Trichomonas vaginalis antigen by EIA test performed. d. There was no documented test request from an individual authorized to order or receive test results for the Trichomonas vaginalis antigen by EIA test performed for Patient #1. 2. Review of policy/procedure titled: "Wet Mount Examination," policy/procedure number "HEM.04.080," approved by the laboratory director on 11-9-2016 did not indicate wet mount tests were to be sent to a reference laboratory to confirm a positive Trichomonas result from a wet mount. 3. In interview on 2-5-2020 at 3:58 PM, SP6 (Director of Laboratory Services) confirmed there was no documented test request from an authorized individual for the Trichomonas vaginalis antigen by EIA test.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

	procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on document review and interview the laboratory failed to ensure personnel followed two of two testing procedures reviewed ("Wet Mount Examination" and "Routine Urinalysis,") for reporting of sperm found in wet mount and urinalysis tests (refer to D5401).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on document review and interview the laboratory personnel failed to follow two of two testing procedures reviewed ("Wet Mount Examination" and "Routine Urinalysis," for reporting of sperm found in wet mount and urinalysis tests). Findings included: 1. Review of patient test reports for Patient #1 indicated the following: a. The patient was a female patient. b. The patient had a wet mount test performed on 12-8-2018 at 5:38 PM. The wet mount test report did not indicate sperm was present. The "Emergency Room Report," electronically signed by SP11 (emergency department physician) indicated the laboratory verbally reported sperm was possibly present in the wet mount. c. The patient had a complete urinalysis test performed on 12-8-2018 at 7:06 PM. The urinalysis test report did not indicate the sample was tested for sperm, nor did it indicate the absence or presence of sperm in the sample. The "Nursing Narrative Note," electronically signed by SP15 (Registered Nurse) on 12-8-2018 at 9:34 PM, indicated SP9 verbally reported to SP15 the patient's urine sample was tested for sperm and there was no sperm noted. 2. Review of policies and procedures indicated the following: a. Policy/procedure titled: "Wet Mount Examination," signed by the laboratory director on 11-9-2016 read: "The wet mount may also be used to identify spermatozoa, particularly in cases of sexual assault." The policy/procedure did not indicated the presence or absence of sperm was to be reported verbally. b. Policy/procedure titled: "Routine Urinalysis," signed by the laboratory director on 3-21-2018, indicated an order for a complete urinalysis test includes a microscopic examination of the urine sediment. The policy/procedure read: "Report the presence of sperm as present in males only. It is considered a contaminant in routine urinalysis specimens from females and is not reported." The policy /procedure did not indicated the presence or absence of sperm in a female patient was to be reported verbally. 3. In interview on 2-5-2020 at 3:58 PM, SP7 (Hematology Technical Supervisor) confirmed sperm was verbally reported for Patient #1's wet mount and a verbal report was given that no sperm was present in Patient #1's urine.
D5821	TEST REPORT CFR(s): 493.1291(k)

	When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to notify the authorized person who ordered a test of errors in the reported patient test results for three of three corrected reports reviewed (Patients #1, #6, and #7). Findings included: 1. Review of patient test reports indicated the following: a. Patient #1 had a wet mount test performed on 12-8-2018 at 5:38 PM. The test report read: "...Trichomonas, Wet Mount: 1+..." The test result was corrected on 12-9-2018 at 9:16 AM by SP7 (Hematology Technical Supervisor) to "...Trichomonas, Wet Mount: see note..." The "note" read: "Confirmatory testing showed negative for Trichomonas antigen using Enzyme Immunoassay." There was no documentation to indicate the reason for the corrected report, nor was there documentation to indicate the authorized person who ordered the test was notified of the corrected report. b. Patient #6 had an aspartate aminotransferase (AST) test performed on 12-12-2018 at an unknown time. The test result was corrected from less than 5 units per liter (U/L) to 39 U/L on 12-27-2018 at 12:44 PM by SP12 (General Supervisor). An "Error Correction Report" form indicated the error was due to a "technical error." There was no documentation to indicate the authorized person who ordered the test was notified of the corrected report. c. Patient #7 had a urinalysis test performed on 12-4-2018 at an unknown time. The test results were corrected to "see note" on 12-5-2018 at 4:56 AM. An "Error Correction Report" form indicated the error was "non-laboratory" related and the error was "caught immediately and corrected." The report further indicated the nurse "used wrong source" and the sample was recollected. There was no documentation to indicate the authorized person who ordered the test was notified of the corrected report. 2. Review of policy/procedure titled: "Corrected Laboratory Results," policy number unknown, approved by the laboratory director on 8-6-2018, did not require the laboratory to notify the authorized person who ordered the test of a corrected test report unless the correction was due to releasing results "...on the wrong patient chart..." 3. In interview on 2-5-2020 at 4:25 PM, SP6 (Director of Laboratory Services) indicated the laboratory followed their procedure titled "Corrected Laboratory Results" when a patient test report is corrected. SP6 confirmed corrected reports for patients #1, #6, and #7 should have been phoned to either the ordering physician or nursing floor (if the patient was an inpatient).