Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2055145	10/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Optumcare New Mexico Llc Journal Center Urgent	5150 Journal Center Blvd Ne, Albuquerque, NM	

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	During a recertification survey completed on 10/14/2020 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 493.1403 Laboratory Director, Moderate Complexity 493.1409 Technical Consultant, Moderate Complexity
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of the Point-of-Care Testing General Policy and interview with the Technical Consultant, the laboratory failed to have a written policy for assessing the competency of the Technical Consultant. Findings are: A. Review of the Point-of-Care Testing General Policy including competency dated 01/2016 indicated no policy or process for evaluating the competency of the Technical Consultant: B. During the exit conference on 10/14/2020 at 01:00 pm, the Technical Consultant stated Technical Consultant competency wasn't required and not performed.
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 the review of laboratory procedures, Point of Care Testing General Policy, Training and Competency Checklists and Quizzes, email from the Technical Consultant and interview with the Clinic Supervisor, the laboratory failed to establish a written policy for documenting and reporting critical or panic values. Findings are: A. Review of the Abbott i-STAT chemistry analyzer Troponin tests (used to identify proteins associated with heart muscle damage) and the HemoCue WBC (White Blood Cell Count) procedures revealed a lack of a detailed protocol for documenting critical results or panic, values that were immediately, verbally communicated to the provider caring for the patient. 1. Abbott i-STAT Troponin (dated 10/03/2018) and HemoCue WBC (reviewed by the Laboratory Director on 08/19/2020) procedures failed to: a. define the critical values and how to document the communication of the critical result in the LIS (Laboratory Information System) or in a written report. b. provide a step-by-step instruction for verification of the critical test results including repeating the test, sending a sample to a reference laboratory or consulting with the patient's provider. B. Review of the Point of Care Testing General Policy (reviewed by the Laboratory Director in 09/2020), section 9, labeled QA/QI Monitors and Reports, stated "Confirmation of critical values as required by procedures and policies." 1. Review of the Point of Care Testing General Policy failed to outline the process for the "confirmation of critical values" as referenced in the Point of Care Testing General Policy. 2. Review of Point of Care Testing monthly QA (Quality Assurance) Reports (December 2019 and January 2020) revealed no documentation of an assessment of adherence to critical value policies. C. Review of the Training and Competency Checklist and Competency Quizzes in 2020 revealed no documentation that testing personnel are trained to identify a critical value, report, and document the immediate, verbal communication to the physician caring for the patient. 1. The i-STAT Troponin Training and Competency checklist (dated 08/01/2018) verifies that testing personnel "tests patient samples, evaluates, and records results." 2. The i-STAT Troponin Competency Quiz (dated 08/2018) did not contain questions to asses the knowledge or the ability to recognize critical values. 3. The HemoCue Training and Competency checklist (dated 08/31/2018) did not include anything regarding the process of how to handle a critical value. 4. The HemoCue Competency Quiz (dated 02/07/2020) did not contain questions to access the knowledge or the ability to recognition of critical values. D. During interview on 10/08/2020 at 03:18 pm, the Clinic Supervisor was asked if the facility had a written policy or procedure detailing how the site communicates and documents any critical or panic values to the physician. The Clinic Supervisor stated that every assay (test) and patient report, has the expected normal ranges listed and that "all the testing personnel knew and were trained to communicate all test results to the physician as soon as possible, regardless if it was within the normal range or not." E. Review of an email from the Technical

	Consultant dated 10/14/2020 indicated the following: "[Name of Surveyor], there is not a separate policy but there are sections within the general policy and procedure (which is currently being rewritten to meet [Corporate Name] standards). Each procedure defines the QA/QI(Quality Assessment) requirements for that test. "
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the review of patient test logs, instrument print outs, laboratory policy and interviews with laboratory staff, the laboratory failed to ensure the positive identification of patient samples and test results in the test record. 34 of 164 patients tested on 12/15/2019 - 12/21/2019, 01/06/2020 - 01/09/2020 and 09/09/2020, failed to meet the minimum requirements for positive patient identification. Findings are: A. Review of the laboratory's Point-of-Care Testing General Policy dated 01/2016 indicated: "2.2 Patients will be identified using 2 identifiers prior to the performance of any POC (Point of Care), according to the [Corporate Name] Patient Identification Policy. 2.3 Patient specimens will be labeled with full name and Medical Record (sic) and time of collection as well as any printout if result is obtained from an instrument." B. Review of patient test logs revealed the laboratory failed to follow laboratory policy and use 2 patient identifiers throughout the testing process. The log requested the following documentation for each patient: Patient Name, Test, Results, UA (urinalysis) printout taped to log, and the i-STAT Chemistry Analyzer printouts for the Chem 8+ and Troponin tests taped to the log. There was no place on the log to record the the MRN (Medical Record Number) or other identifier such as date of birth on the log. Instruments printouts were taped in layers, one on each line, corresponding to 1 of a possible 14 patients per sheet. There were no instrument printouts for the other tests performed; Streptococcus A, hCG (pregnancy), Influenza A & B, Mononucleosis, (WBC) White Blood Cell count, and RSV (Respiratory Synclinal Virus). 1. 12/15/2019 7 (POC102 - POC107 and POC150) of 9 (POC102 - POC108, POC149 and POC150) patients tested only had the first name and initial on the log. 2 patients (POC105 and POC107) had a Troponin ordered but the printouts were not attached to the log. Only 1 patient, (POC106), had a first name written on the corresponding UA printout with a Medical Record Number. 2. 12/16/2019 6 (POC63, POC68, POC70, POC74, POC79, POC87) of 27 (POC60 - POC87) patients tested had only the first name and last initial on the log. 1 patient, POC67, had a first initial and last name. 3. 12/19/2019 9 (POC151 - POC155, POC159, POC161, POC162, POC164) of 14 (POC151 - POC164) patients were listed on the log by first name and initial. 1 patient, POC162 was identified by first name only. Only 1 patient, POC155, had a corresponding UA printout labeled with the first name and initial. 4. 01/06/2020 1 (POC24) of 24 patients, POC6 - POC29, was listed by first name only. 5. 01/07 /2020 1 (POC35) of 8 patients, POC33 - POC40, was listed by first name and last initial only. 6. 01/08/2020 5 (POC42, POC43, POC46, POC51 and POC59) of 14 patients, POC46 - POC59 had a first name and initial. 1 (POC44) of 14 patients, POC46 - POC59 had a first name only. 1 (POC45) of 14 patients, POC46 - POC59,

	had an initial and a last name. There was no corresponding printout for patient POC53 for the Troponin. C. The laboratory manually recorded the WBC result for all patients tested because the analyzer was not directly connected to the EMR (Electronic Medical Record) nor did it have a printed result. A second identifier was not recorded on the test log for 2 of 2 patients tested 12/15/2019 - 12/21/2019, 01/06/2020 - 01/09 /2020 and 09/09/2020. The laboratory reported performing 200 WBC tests per year. 1. Patient POC63 - 12/16/2019. The only identifier recorded was the patient's first name and initial. 2. Patient POC31 - 09/09/2020. The patient's first and last name was recorded but not the MRN. D. During interview on 10/07/2020 at 3:00 pm, the Clinic Supervisor stated the providers review the patient test results from the patient log rather than from the EMR (Electronic Medical Record). He also stated that the he used the Daily Schedule in the EMR to find the entire name of the patient and then the MRN to find the corresponding laboratory results in the EMR. D. During the exit conference 10/14/2020 at 01:00 pm, the Technical Consultant stated that the MRN on the instrument printout was the second identifier.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on the review of patient result logs, instrument printouts, and interview with the Clinic Supervisor, the laboratory failed to have a system to ensure the accuracy of test results manually entered into the Electronic Medical Record (EMR). Findings are: A. The laboratory failed to ensure the positive identification of patient samples and test results in the test record. 34 of 164 patients reviewed for the following dates 12/15 /2019 - 12/21/2019, 01/06/2020 - 01/09/2020 and 09/09/2020, failed to meet the minimum requirements for positive patient identification. B. Review of the instrument printouts for i-STAT Chem 8+ chemistry and Troponin revealed the printouts contained documentation of the patient MRN (Medical Record Number) and an operator identification number. 1. I-STAT patient test strips are manually taped to daily log, on the same line of entry, to indicate that the result strip belongs to the same patient that was hand written on the same line of entry on the log. The test results are manually entered into the EMR. 2. HemoCue hemoglobin results are not printed or transmitted electronically to the EMR but are manually written on the daily log and entered into the EMR. C. During interview on October 8, 2020 at 03:25 pm, when asked if the laboratory had an existing, written policy or practice to verify that manual results were entered correctly, the Clinic Supervisor stated no.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory policies, patient test logs, monthly quality assessments, personnel records, pre-survey documents, microscope maintenance records, observation, and interviews with the laboratory staff, the Laboratory Director failed to provide overall direction and management of the laboratory, Findings are: A. The Laboratory Director failed to approve, in writing, the discontinuance of the KOH (Potassium Hydroxide) procedure. See D6007 B. The Laboratory Director failed to ensure that an effective quality assessment program was established and followed. See D6021
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, patient test logs, monthly quality assessments, personnel records and interviews with the laboratory staff, the Laboratory Director failed to ensure that the responsibilities delegated to the Technical Consultant were properly performed. Findings are: A. The laboratory failed to have policies that assess the competency of the Technical Consultant. See D5209 B. The laboratory failed to ensure positive patient identification in the test records. See D5787 C. The monthly quality assessment performed by the Technical Consultant did not assess compliance with patient identification or accuracy of the test records. See D5787 and D5801 D. The laboratory failed to have a policy for handling critical or life-threatening test results. See D5403
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:

	Based on the review of laboratory policies, pre-survey documents, patient test logs, microscope maintenance records, observation, and interviews with laboratory staff, the Laboratory Director failed to approve, in writing, the discontinuance of the KOH (Potassium Hydroxide) procedure. Findings are: A. Review of the pre-survey documents completed and submitted by the Technical Consultant on 10/01/2020 indicated the laboratory performed 100 KOH preps (used to identify fungal elements from vaginal or skin samples) per year. B. Observation of the laboratory area on 10/07 /2020 at 09:17 am confirmed the laboratory had the equipment (microscope) and supplies (10% KOH droppers) to perform the test. C. Review of maintenance records revealed continued daily cleanings for the microscope throughout 2020. D. Review of laboratory policy, Provider Performed Microscopy Procedures last reviewed 01/2016, had no documentation indicating the test was no longer performed in the laboratory. E. Observation of the laboratory on 10/07/2020 at 02:15 pm revealed the KOH droppers had been removed from the laboratory since the previous observation at 09: 17 am. F. During interview on 10/07/2020 at 02:30 pm, the Clinic Supervisor stated that he didn't know anything about the KOH droppers and their removal. He stated in a later interview at 03:02 pm, that the providers didn't want to perform the bi-annual competency testing so the the test was discontinued 1- 2 years ago. G. Review of patient testing logs, 12/15/2019 - 12/21/2019, 01/06/2020 - 01/09/2020 and 09/09 /2020, had no record of KOH testing. H. During interview on 10/14/2020 at 07:18 am, Provider #1 stated that she was the only women's health provider for the clinic and she did not use the microscope for testing. She further stated that the provider that used the microscope left the clinic 1 - 1 1/2 years ago. I. During the exit conference on 10 /14/2020 at 01:00 pm, the Technical Consultant stated that she thought she could leave the test available just in case a future provider wanted to start testing.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, patient test logs, monthly quality assessments, personnel records and interviews with the laboratory staff, the Laboratory Director failed to ensure that an effective quality assessment program was established and followed. Findings are: A. The monthly quality assessment performed by the Technical Consultant did not assess compliance with patient identification or accuracy of the test records. See D5787 and D5801 B. Policy and procedure manuals were not updated to reflect the current test menu. See D5403
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on the review of laboratory policies, pre-survey documents, patient test logs, microscope maintenance records, instrument printouts, laboratory policies and procedures, personnel records, email from the Technical Consultant, observation, and interviews with laboratory staff, the Technical Consultant failed to provide technical oversight of the laboratory. Findings are: A. The Technical Consultant failed to establish a quality control program that ensured acceptable levels of performance for accuracy of manually reported test results, critical values, and positive patient identification in the test records. See D6042 B. The Technical Consultant failed to remove the KOH (Potassium Hydroxide) procedure when testing was no longer performed in the laboratory. See D6039
D6039	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(1) The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on the review of laboratory policies, pre-survey documents, patient test logs, microscope maintenance records, observation, and interviews with laboratory staff, the Technical Consultant failed to remove the KOH (Potassium Hydroxide) procedure when testing was no longer performed in the laboratory. Findings are: A. Review of the pre-survey documents completed and submitted by the Technical Consultant on 10/01/2020 indicated the laboratory performed 100 KOH preps (used to identify fungal elements from vaginal or skin samples) per year. B. Observation of the laboratory area on 10/07/2020 at 09:17 am confirmed the laboratory had the equipment (microscope) and supplies (10% KOH droppers) to perform the test. C. Review of maintenance records revealed continued daily cleanings for the microscope throughout 2020. D. Review of laboratory policy, Provider Performed Microscopy Procedures last reviewed 01/2016, had no documentation indicating the test was no longer performed in the laboratory. E. Observation of the laboratory on 10/07/2020 at 02:15 pm revealed the KOH droppers had been removed from the laboratory since the previous observation at 09:17 am. F. During interview on 10/07/2020 at 02:30 pm, the Clinic Supervisor stated that he didn't know anything about the KOH droppers and their removal. He stated in a later interview at 03:02 pm, that the providers didn't want to perform the bi-annual competency testing so the the test was discontinued 1- 2 years ago. G. Review of patient testing logs, 12/15/2019 - 12/21/2019, 01/06/2020 - 01/09/2020 and 09/09/2020, had no record of KOH testing. H. During interview on 10/14/2020 at 07:18 am, Provider #1 stated that she was the only women's health provider for the clinic and she did not use the microscope for testing. She further stated that the provider that used the microscope left the clinic 1 - 1 1/2 years ago. I. During the exit conference on 10/14/2020 at 01:00 pm, the Technical Consultant stated that she thought she could leave the test available just in case a future provider wanted to start testing.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for

	acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of patient result logs, instrument printouts, laboratory policies and procedures, personnel records, email from the Technical Consultant and interviews with laboratory staff, the Technical Consultant failed to establish a quality control program that ensured acceptable levels of performance for accuracy of manually reported test results, critical values, and positive patient identification in the test records. Findings are: A. The laboratory failed to have a system to ensure the accuracy of test results manually entered into the Electronic Medical Record (EMR). See D5801 B. The laboratory failed to establish a written policy for documenting and reporting critical or panic values. See D5403 C. The laboratory failed to ensure the positive identification of patient samples and test results in the test record. 34 of 164 patients tested on 12/15/2019 - 12/21/2019, 01/06/2020 - 01/09/2020 and 09/09/2020, failed to meet the minimum requirements for positive patient identification.