Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0177137	08/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
East Liberty Family Health Care Center	7157 Mary Peck Bond Place, Pittsburgh, PA	

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
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 review of laboratory procedure manuals and interview with the director of nursing, the laboratory failed to establish a procedure to assess the competency of 9 of 10 TP who performed Fern, KOH and wet mount microscopic examinations in 2017 and 2018, and 2019. Findings include: 1. On the day of survey, 08/05/2019, the laboratory failed to provide a written policy on how to assess the competency of 9 of 10 TP who performed Fern, KOH and wet mount microscopic examinations from 01 /01/2017 to 08/05/2019. 2. The laboratory failed to assess the competency of 9 of 10 TP who performed KOH, fern and wet mount microscopic examinations in 2017 and 2018, and 2019. 3. The director of nursing confirmed the findings above on 08/05 /2019 around 1:30 pm. *** KOH= Potassium Hydroxide
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 review of the laboratory procedures and interview with the director of nursing, the laboratory failed to have a complete procedure manual required for urine sediment microscopic examination from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/05/2019, review of the laboratory's procedure manual revealed, the laboratory's urine sediment microscopic examination policy did not include the following from 01/01/2017 to 08/05/2019: - Step-by-step performance of the procedure, including interpretation of results. - Preparation of slides, solutions, controls, reagents, and other materials used in testing. - Control procedures. - Pertinent literature references. - The laboratory's system for entering results in the patient record and reporting patient results. 2. The director of nursing confirmed the findings above on 08/05/2019 around 3:00 pm.
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 review of room temperature records and interview with the director of nursing, the laboratory failed to document room temperature records where 2 of 2 boxes of Troy Biological inc. Uri-Check CLED/ EMB media were stored from 2017 to the date of survey. Findings Include: 1. Troy Biological inc. Uri-Check CLED/ EMB media package insert states "store at 2-25 degrees Celsius". 2. On the day of survey, the laboratory could not provide documentation of room temperature records where 2 of 2 boxes of Troy Biological inc. Uri-Check CLED/ EMB media were stored from 01/01/2017 to 08/05/2019. 3. In 2017, 45 urine culture specimens were examined. 4. In 2018, 45 urine culture specimens were examined. 5. In 2019 (01/01 /2019 to 08/05/2019), 55 urine culture specimens were examined. 5. The director of nursing confirmed on 08/05/2019 around 02:45 pm, daily room temperatures were not documented. ***CLED = Cystine Lactose Electrolyte-Deficient. ***EMB = Eosin methylene blue.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, and interview with director of nursing, the laboratory failed to document QC procedures performed on 2,450 of 2,450 urine sedimentation, KOH, wet mount and fern microscopic examinations from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/05/2019, the laboratory could not provide documentation of QC performed on 30 of 30 urine sedimentation, 840 of 840 KOH, 1,400 of 1,400 wet mount and 35 of 35 fern microscopic examinations performed from 01/01/2017 to 08/05/2019. 2. In 2017, 15 urine sedimentation, 310 KOH, 550 wet mount and 20 fern specimens were examined. 3. In 2018, 10 urine sedimentation, 350 KOH, 600 wet mount and 10 fern specimens were examined. 4. In 2019 (01/01/2019 to 08/05/2019), 5 urine sedimentation, 180 KOH, 250 wet mount and 5 fern specimens were examined. 5. The director of nursing confirmed on 08/05/2019 around 03:21 pm, that QC was performed but not documented. *** KOH = Potassium Hydroxide
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the media check records and interview with the director of nursing, the laboratory failed to perform and document quality control for each batch or shipment of Troy Biological inc. Uri-Check CLED/ EMB media's ability to support growth, used for 145 of 145 urine culture specimens from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/05/2019, the laboratory could not provide documentation of quality control performed on each batch or shipment of Troy Biological inc. Uri-Check CLED/ EMB media for its ability to support growth from 01/01/2017 to 08/05/2019. 2. In 2017, 45 patient urine culture specimens were examined. 3. In 2018, 45 patient urine culture specimens were examined. 4. In 2019 (01/01/2019 to 08/05/2019), 55 patient urine culture specimens were examined. 5. The director of nursing confirmed on 08/05/2019 around 12:45 pm, that QC was not performed. ***CLED = Cystine Lactose Electrolyte-Deficient. ***EMB = Eosin methylene blue.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on American Academy of Family Physicians (AAFP) proficiency testing (PT) result records and interview with the director of nursing, the laboratory director (LD) failed to ensure that all proficiency testing reports received, identify any problems that required corrective actions for unsatisfactory results from 2017 (1 out of 3 events), 2018 (3 of 3 events) and 2019 (2 of 3 events). Findings Include: 1. On the day of survey, 08/05/2019, review of AAFP PT records revealed no corrective actions were documented for the following unsatisfactory scores: AAFP 2017 1st event 75% score for urine sediment microscopic examination and 66% for urine culture examination. AAFP 2018 1st event 20% score for urine culture examination. AAFP 2018 2nd event 75% score for urine sediment microscopic examination. AAFP 2018 3rd event 75% score for urine sediment microscopic examination. AAFP 2019 1st event 50% score for urine sediment microscopic examination. AAFP 2019 2nd event 75% score for urine sediment microscopic examination. 2. The director of nursing confirmed the findings above on 08/05/2019 around 01:00 pm.
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 records and interview with the director of nursing, the laboratory failed to ensure quality assessment (QA) programs were maintained and documented to assure the quality of laboratory from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/05/2019, the laboratory could not provide a policy that described the frequency in which QA activities were performed and assessed. 2. The 2017 monthly QA activity forms provided were not signed by the laboratory director. 3. The laboratory could not provide QA activities performed to assess the laboratory's pre-analytical, analytical and post-analytical activities in 2018 and 2019. 4. The director of nursing confirmed the findings above on 08/05/2019 around 2:49 pm.