Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	14D2009997	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Repro Health Srvcs Of Planned Parenthood Of St L	317 Salem Place, Fairview Heights, IL	

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
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: A. Based on review of laboratory records and personnel interviews; the laboratory failed to outline all required components of a test procedure for the specialty of microbiology. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Preparation of Microscopic Wet Smear" for vaginal wet preps with and without potassium hydroxide (KOH). 2. Review of the procedure, "Preparation of Microscopic Wet Smear", found the procedure failed to outline the following required components of a test procedure: a. Control procedures. b. The reportable range for test results. c. Description of the course of action to take if a test

	system becomes inoperable. 3. Interview with TP#2 and quality assurance representative on 2-22-2018 at 2:00 pm confirmed the above findings. B. Based on review of laboratory records and personnel interviews; the laboratory failed to outline all required components of a test procedure for the specialty of hematology. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Qualitative Semen Analysis Specimen". 2. Review of the procedure, "Qualitative Semen Analysis Specimen", found the procedure failed to outline the following required components of a test procedure: a. Control procedures. 3. Interview with TP#2 and quality assurance representative on 2-22-2018 at 2:00 pm confirmed the above findings.
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 direct observations, laboratory records and interview with laboratory personnel; the laboratory used supplies for the specialty of microbiology which were expired for patient testing. Findings Include: 1. During tour of laboratory testing facility on 2-22-2018 at 10:25 am with testing personnel (TP) #2, the surveyor observed the reagent, 20% potassium hydroxide (KOH), used for vaginal wet prep testing was expired. a. Reagent - Potassium Hydroxide, 20% Lot #1701713, Expiration Date: 10-03-2017 2. Review of 2 of 4 patient test results for vaginal wet mount testing were performed with the expired 20% KOH reagent. Patient Identification Test Date P8 01-22-2018 P9 02-02-2018 3. Interview with TP#2 and the quality assurance representative on 2-22-2018 at 2:00 pm confirmed the above findings.
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 laboratory records and interview with laboratory personnel; the laboratory failed to perform positive and negative controls for qualitative semen analysis testing for 3 of 3 patient test dates reviewed. Findings Include: 1. Review of the laboratory procedure manual identified the procedure, "Qualitative Semen Analysis Specimen", which failed to indicate control procedures for qualitative semen analysis. See D5403. 2. Review of qualitative semen analysis patient test reports for 3 of 3 patient test dates found no quality controls were performed or documented. Patient Identification Test Date P10 08-11-2017 P11 06-08-2017 P12 07-17-2017 3.

	Interview with TP#2 and the quality assurance representative on 2-22-2018, at 2:00 pm, confirmed no quality control procedures are performed for qualitative semen analysis.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observations, laboratory records and personnel interviews; the laboratory failed to demonstrate potassium hydroxide(KOH) reagent performs within the specifications established by the laboratory for vaginal wet prep testing. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Preparation of Microscopic Wet Smear", which failed to indicate the control procedures to ensure KOH reagent performs within the specifications established by the laboratory. See D5403. 2. During tour of laboratory testing facility on 2-22-2018 at 10:25 am with testing personnel (TP) #2, the surveyor observed the reagent, 20% potassium hydroxide (KOH), Lot #1701713. 3. Review of laboratory quality control records failed to document KOH, Lot#1701713, meets performance specifications. 4. Interview with TP#2 and the quality assurance representative on 2-22-2018, at 2:00 pm, confirmed performance specifications were not documented with each new lot of KOH reagent.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review laboratory records and personnel interviews; the laboratory director failed to specify in writing the responsibilities and duties for 3 of 9 testing personnel listed on the CMS-209. Findings Include: 1. No duties and responsibilities were specified in writing for 3 of 9 testing personnel (TP) listed on the CMS-209. a. TP#3,

	4, and 8. 2. On survey date 2-22-2018, at 2:00 pm, TP#2 and the quality assurance representative confirmed that there were no documents specifying the duties and responsibilities for 3 of 9 TP.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the technical consultant (TC) failed to ensure annual competency assessments were completed for all testing personnel performing mycology and hematology testing. Findings Include: 1. Review of competency assessment records for 3 of 3 testing personnel (TP) performing vaginal wet preps and qualitative semen analysis found no documented competency assessments in 2016 and 2017 for either procedure performed by the laboratory. 2. On survey date 2-22-2018, at 2:00 pm, TP#2 and the quality assurance representative confirmed that there were no competency assessment documents available for review for 3 of 3 TP performing vaginal wet preps and qualitative semen analysis.