

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2012836	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier Washington Reproductive Laboratories	Street Address, City, State 2531 Cowan Blvd, Fredericksburg, VA	
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	An announced on-site CLIA recertification survey was conducted at Washington Reproductive Laboratories on September 21, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on September 2, 2021 and virtual record review conducted on September 9, 2021. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The specific deficiencies are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems, D6076 - 42 C.F.R. 493.1403 Condition: High Complexity Laboratory Director.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, Proficiency Testing (PT) records, accuracy verification records, lack of documentation and interview, the laboratory failed to verify the accuracy of their complete semen analysis panel testing twice annually in calendar year 2020. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing Procedure (PT) Policy", with statements, "D. Alternative Performance Assessment-Alternative Assessment is performed on: Pre-stained Slides for Sperm Morphology; Semen Analysis..." and F. PT Procedure (COM.01000) - 2. Proficiency testing through AAB is conducted twice a year for andrology and embryology. - a. For andrology proficiency testing we are enrolled for sperm count and sperm morphology." 2. Review of the laboratory's Proficiency testing (PT) and accuracy verification records revealed a lack of PT enrollment and lack of documentation of "twice a year" accuracy verification for semen analysis in calendar year 2020. The surveyor</p>

	<p>requested to review documentation of the "twice a year" accuracy verification for calendar year 2020. The laboratory provided no documentation for review. 3. In an exit interview with the primary testing personnel on September 21, 2021 at approximately 11:00 AM, the findings were confirmed.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies and procedures, temperature logs, quality control (QC) records, Quality Assessment (QA) documents, patient records, lack of documentation and interviews, the laboratory failed to: 1. follow their established policy to take daily room and incubator temperatures from June 2019 to May 2020 (see D5401); 2. follow their established policy and perform QC procedures each day of patient testing for sperm counts from June 11, 2019 to August 23, 2021 (see D5447-REPEAT DEFICIENCY); 3. identify and address analytic issues within the specialty of hematology (see D5791-REPEAT DEFICIENCY).</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, temperature logs, lack of documentation and interview, the laboratory failed to follow their established policy to take daily room and incubator temperatures from June 2019 to May 2020. The findings include: 1. Review the laboratory's policies and procedures revealed a procedure, "2. QC Procedure", with a statement, "1. Laboratory personnel must take daily temperature readings of the andrology laboratory, IVF/IUI incubators, Makler warmer..." 2. Review of the laboratory's temperature logs from June 2019 to September 2021 revealed a lack of documentation of the andrology laboratory's incubator and room temperature readings from June 2019 until May 2020. The surveyor requested to review the incubator and room temperature readings from June 2019 until May 2020. The laboratory provided no documentation for review. 3. In an exit interview with the primary testing personnel on September 21, 2021 at approximately 11:00 AM, the findings were confirmed.</p>
<p>D5447</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p>

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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

****REPEAT DEFICIENCY**** Based on the review of the laboratory's policy's and procedures, quality control (QC) records, patient records and interview, the laboratory failed to follow their established policy and perform QC procedures each day of patient testing for sperm counts for thirty-nine (39) days from June 11, 2019 to August 23, 2021 when performing testing for fifty-five (55) patients. Findings include: 1. Review of the laboratory's policies and procedures revealed a procedure, "C.II. b. Makler Chamber QC with Latex Beads", with a statement. "Procedure-1. The latex beads quality control check should be performed each day prior to the evaluation of actual sperm samples." 2. Review of the laboratory's QC records and patient records from June 2019 to the date of the survey, September 21, 2021, revealed a lack of documentation of the "latex beads" QC for the following dates: 06/11/2019-1 patient; 06/18/2019-1 patient; 07/11/2019-1 patient; 08/28/2019-1 patient; 11/19/2019-1 patient; 12/17/2019-2 patients; 01/08/2020-2 patients; 01/22/2020-1 patient; 02/12/2020-1 patient; 02/29/2020-1 patient; 03/13/2020-1 patient; 05/21/2020-1 patient; 06/04/2020-1 patient; 06/18/2020-1 patient; 06/25/2020-1 patient; 07/07/2020-2 patients; 07/28/2020-2 patients; 08/26/2020-2 patients; 09/02/2020-1 patient; 09/09/2020-3 patients; 09/30/2020-1 patient; 12/08/2020-2 patients; 12/22/2020-1 patient; 01/12/2021-2 patients; 02/16/2021-3 patients; 03/23/2021-1 patient; 03/30/2021-1 patient; 04/13/2021-1 patient; 05/11/2021-2 patients; 05/18/2021-1 patient; 06/08/2021-1 patient; 06/15/2021-1 patient; 06/22/2021-2 patients; 07/06/2021-2 patients; 07/15/2021-1 patient; 07/27/2021-1 patient; 08/10/2021-2 patients; 08/17/2021-1 patient and, 08/24/2021-2 patients. A total of 39 days with no QC and 55 patients reported. The surveyor requested to review QC documentation for the above listed dates. The laboratory provided no documentation to review. 3. In an exit interview with the primary testing personnel on September 21, 2021 at approximately 11:00 AM, the findings were confirmed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

****REPEAT DEFICIENCY**** Based on the review of the Quality Management (QM) plan, QA Quality Assessment audits, laboratory's policies and procedures, lack of documentation and interviews, the laboratory's established QA plan failed to identify and address analytic issues in the specialty of Hematology from June 2019 to September 2021 (Cross Reference D5401 and D5447). Findings include: 1. Review of the laboratory's policies and procedures, temperature logs, QC records and interviews revealed a lack of documentation of: -the daily room and incubator temperatures from June 2019 to May 2020 (Cross Reference D5401); and -"latex bead" QC each day of

	<p>patient testing from June 2019 to September 2021 (Cross Reference D5447). 2. Review of the laboratory's "Quality Management Plan" revealed the following statement: "C. QM Indicators of Quality (GEN.20316)-The WFC (Washington Fertility Clinic) QM monitors indicators of quality in the pre-analytic, analytic and post-analytic phases by regularly comparing performance against targets defined by the laboratory." The surveyor requested to review documentation of the QM monitors from June 2019 to September 2021. The laboratory provided no documentation for review. 3. In an exit interview with the primary testing personnel on September 21, 2021 at approximately 11:00 AM, the findings were confirmed.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies and procedures, temperature logs, quality control (QC) records, Quality Assessment (QA) documents, patient records, lack of documentation and interviews, the laboratory director failed to ensure: 1. quality control procedures were followed each day of patient testing for sperm counts (see D6093); 2. the Quality Management Program was maintained from June 2019 to September 2021 (see D6094).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, quality control (QC) records and interviews, the lab director failed to ensure that the quality control procedures were followed each day of patient testing for sperm counts for thirty-nine (39) days from June 11, 2019 to August 23, 2021 (Cross Reference D5447).</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Quality Management Program" records, quality control (QC) records, patient records and interview, the laboratory director failed to ensure the Quality Management Program was maintained from June 2019 to September 2021 (Cross Reference D5447).</p>