Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0900412	05/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Michael C Doody Md	220 Fort Sanders West Blvd, Bldg 2, Ste 106, Knoxville, TN	

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 the laboratory's submitted Form CMS 209, review of the laboratory's policies and procedures, review of the laboratory's competency assessment records, and interview with both technical consultants, it was determined that the laboratory failed to have documentation of policy to perform competency assessments on the technical supervisor and general supervisor. Findings include: 1. Review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical supervisor and 1 general supervisor. 2. Review of the laboratory's policies and procedures revealed the facility failed to have documentation of a policy addressing performing competency assessments on supervisors. 3. Review of 2020, 2021 and 2022 competency assessments revealed no documentation of competency for technical supervisor and general supervisor. 4. Interview at 1:15 P.M. on May 11, 2022 in the break room with both technical consultants confirmed the above findings. ==========
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: ========== Based on review of the American Proficiency Institute (API) proficiency testing survey results evaluation, the laboratory policy titled "Proficiency Testing", and interview with technical consultant #1, determined the laboratory failed to verify the accuracy of analytes not evaluated or scored by a CMS-approved proficiency testing program for sperm classification for 2 of 7 events (2020 Event 3 and 2022 Event 1). The findings include: 1. Review of the API proficiency testing survey results evaluation revealed the following events with ungraded performance: a. Hematology 2020 Event 3 Sperm classification Sample SCL-12 Reported result: Abnormal Expected result: See commentary Performance: Not graded Sample SCL-14 Reported result: Borderline Expected result: Normal Performance: Not graded Sample SCL-15 Reported result: Immature germinal cell Expected result: See commentary Performance: Not graded Sample SCL-19 Reported result: Abnormal Expected result: See commentary Performance: Not graded Further review of the API "Performance Review and Corrective Action" form revealed the following statement for corrective action taken: "SCL-18 and SCL-20 were unacceptable-will let Dr. Doody review slides again." b. Hematology 2022 Event 1 Sperm classification Sample SCL-01 Reported result: Abnormal Expected result: See commentary Performance: Not graded Sample SCL-04 Reported result: Borderline Expected result: See commentary Performance: Not graded Sample SCL-05 Reported result: Abnormal Expected result: See commentary Performance: Not graded Sample SCL-09 Reported result: Normal Expected result: See commentary Performance: Not graded Further review of the API "Performance Review and Corrective Action" form revealed no statement for corrective action taken. 2. Review of the laboratory policy titled "Proficiency Testing," states, "Any PT challenges that were submitted and not graded or were not submitted are scored 0% and must be investigated to determine the cause of the failure. Results that were not graded are compared to the results on the Summary Report. This investigation and comparison are signed by the director and filed along with the Summary Report. Any unacceptable results are investigated in the same manner as described above." 3. Interview with technical consultant #1 at 1:15 P. M. on May 11, 2022 in the breakroom, confirmed the laboratory failed to verify the accuracy of analytes not evaluated or scored by a CMS-approved proficiency testing program for sperm classification on 2020 Event 3 and 2022 Event 1. ==========
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: ========== Based on a review of manufacturer's instructions, the laboratory's "Beckman Coulter Access 2 Immunoassay System" policy and procedure, patient reports, and an interview with both technical consultants, the laboratory failed to follow the manufacturer's instructions for

	specimen stability and storage and failed to establish acceptable stability and storage requirements for 8 of 20 patient samples on 2.23.2021, 1 of 17 patient samples on 3.23.2021 and 5 of 14 patient samples on 3.30.2021. a. Review of the Beckman Coulter Access 2 Immunoassay package insert for the prolactin, testosterone, DHEA, TPO antibody, thyroglobulin antibody, CA125 (OV125), and Insulin stated that the maximum sample temperature at -20C was "undetermined." b. Review of the laboratory's "Beckman Coulter Access 2 Immunoassay System" policy and procedure stated, "Refer to the Beckman Coulter training manual for detailed instructions for each assay." Assays performed include: Estradiol, BHCG, Prolactin, TSH, TPO ab, Progesterone, LH, Testosterone, FT4, TG ab, Insulin, FSH, DHEA, and CA125. c. Review of patient reports from 2.23.2021, 3.23.2021, and 3.30.2021, revealed the laboratory tested and reported 14 of 51 patient samples without proper specimen storage and stability requirements. 1. Patient 208193 collected 2.19.2021, CA125 assayed and resulted on 2.23.2021. 2. Patient 30348 collected 2.22.2021, Insulin assayed and resulted on 2.23.2021. 3. Patient 29469 collected 2.22.2021, testosterone and DHEA assayed and resulted on 2.23.2021. 4. Patient 30388 collected 2.19.2021, DHEA, testosterone, TG ab, CA125, and Insulin assayed and resulted on 2.23.2021 5. Patient 294 collected 2.21.2021, CA125 assayed and resulted 2.23.2021 6. Patient 20125 collected 2.22.2021, DHEA, CA125, PRL, Testosterone, and TG ab assayed and resulted on 2.23.2021 7. Patient 30389 collected 2.19.2021, DHEA, PRL, Testosterone, Insulin and CA125 assayed and resulted on 2.23.2021 8. Patient 29538 collected 2.19.2021, DHEA, testosterone, PRL, CA125 assayed and resulted on 2.23.2021 9. Patient 208193 collected 3.22.2021. CA125 assayed and resulted on 3.23.2021 10. Patient 29225 collected 3.29.2021. CA 125 assayed and resulted on 3.30.2021 11. Patient 30431 collected 3.29.2021. DHEA, CA125, PRL, testosterone, TG ab assayed and resulted on 3.30.2021 12. Patient 30421 collected 3.29.2021. DHEA, PRL, testosterone and TG ab assayed and resulted on 3.30.2021 13. Patient 30386 collected 3.29.2021. PRL assayed and resulted 3.30.2021 14. Patient 29225 collected 3.26.2021. Insulin assayed and resulted 3.30.2021 d. An interview with both technical consultants at 2:30 P.M. on May 11, 2022 in the breakroom confirmed that patient samples are frozen if not analyzed on Tuesdays or Thursdays and that no acceptable stability and storage requirements had been established for the following analytes: Estradiol, BHCG, Prolactin, TSH, TPO ab, Progesterone, LH, Testosterone, FT4, TG ab, Insulin, FSH, DHEA, and CA 125. WORD KEY: BHCG= human chorionic gonadotropin TSH= thyroid-stimulating hormone TPO ab= thyroid peroxidase antibody LH= luteinizing hormone FT4= free thyroxine DHEA= dehydroepiandrosterone sulfate CA125= cancer antigen 125 ==========
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: ========== Citation #1 Based on review of

	laboratory freezer logs for the Gibson Refrigerator/freezer combo, model #MRT19GNBW2, Serial # LA50212586 and interview with the general supervisor, determined the laboratory failed to document minimum and maximum temperatures for the frost free freezer for 28 of 28 months (01/2020 through 04/2022). The findings include: 1. Review of freezer logs revealed no documented minimum or maximum temperatures for the frost free freezer. 2. Interview with the general supervisor at 1:10 P.M. on 5.11.2022 in the laboratory confirmed the above findings. Citation #2 Based on direct observation, review of laboratory environmental logs, review of laboratory's Abbott Cell Dyn Emerald Operator's Manual, Revision 9140846F, April 2012, review of laboratory's Beckman Coulter Access 2 Instructions for Use Manual, Revision B14255E, February 2015, and interview with general supervisor, determined the laboratory failed to document laboratory humidity for 28 of 28 months (01/2020 through 04/2022). The findings include: 1. During a tour of the laboratory on 05.11.2022 at 9:30 A.M., the surveyor observed an Abbott Cell Dyn Emerald analyzer and a Beckman Coulter Access 2 on the laboratory counter. 2. Review of laboratory environmental logs revealed laboratory failed to document laboratory room humidity for 28 of 28 months (01/2020 through 04/2022). 3. Review of the laboratory's Abbott Cell Dyn Emerald Operator's Manual, Revision B14255E, February 2015, stated, "maximum relative humidity 80%." 4. Review of the laboratory's Beckman Coulter Access 2 Instructions for Use Manual, Revision B14255E, February 2015, stated "Humidity operational: 20% to 80%." 5. Interview with the general supervisor at 1:10 P.M. on 5.11.2022 in the laboratory confirmed the above findings. ==========
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: ========== Based on observation of Wetprep saline solution containers and interview with both technical consultants, the laboratory failed to label the saline solution containers with lot number, storage requirements and preparation/expiration date for the saline solution in current use. The findings include: 1) Observation of the laboratory on May 11, 2022 at 11:00 A.M. revealed the Wetprep saline solution was stored in red top specimen containers other than the original saline container. The label did not contain a lot number, storage requirement, preparation and expiration date. 2) Interview at 2:00 P.M. on May 11, 2022 in the breakroom with both technical consultants confirmed the above findings. ==========
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: ========== Based on review of laboratory's semen analysis procedure, review of manufacturer's instructions, review of patient test records, review of laboratory's semen analysis quality control (QC) records, and interview with the general supervisor, the laboratory failed to test patient semen analysis in duplicate for 1 of 1 patients tested on 5.4.2022 and 1 of 1 patients tested on 5.11.2022 and test QC material for semen analysis in duplicate for 5 of 5 days in May 2022. The findings include: 1. Review of laboratory's "Semen Analysis Procedure" states "Follow the package insert for Quality Control check for manual sperm counting method using Accu-beads+. QC should be done each day that there is a semen analysis." 2. Review of manufacturer's instructions for the "Accu-bead: Quality Control" revealed the following: "1. Count the beads according to a standard counting procedure. 4. Calculate the bead concentration according to the chamber manufacturer's instructions. 5. Count another aliquot of the same sample. The results should be within 10% of each other to be considered valid. 6. If the results are valid, average the two counts and compare to the Accu-beads acceptable ranges. 7. The counting procedure above should be performed with all Accu-beads concentrations. 8. Record all results along with pertinent information such as the chamber used and the name of the person performing the QC procedure." 3. The following randomly reviewed patients from May 2022, revealed the laboratory failed to test the patient sample in duplicate: a. Collection Date: 5.4.2022 Patient 30797 b. Collection Date: 5.11.2022 Patient 28680 4. Review of laboratory "Sperm Count Quality Control" records for May 2022, revealed the following days Accu-beads quality control was not performed in duplicate: Vial 1 and Vial 2: 5.3.2022, 5.4.2022, 5.5.2022, 5.10.2022, 5.11.2022 The laboratory failed to document quality control manual sperm counts in duplicate for 5 of 5 days in May 2022. 5. Interview with general supervisor at 2:00 P.M. on May 11, 2022 in the breakroom confirmed the above findings. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: ========== Based on review of competency assessment for TP#6 and interview with technical consultant #1, determined Technical Consultant #1(TC#1) failed to evaluate testing personnel TP#6 listed on the CMS Form 209 for Wet Prep analysis. The findings include: 1. Review of 2020, 2021 and 2022 competency assessments revealed no documentation of competency for Wet Prep analysis for TP#6. 2. Interview with TC#1 at 1:30 P.M. on May 11,2022 in the breakroom confirmed the above findings. ==========
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for

	monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: ========== Based on review of competency assessment for TP#2 and interview with technical consultant #1, determined the Laboratory Director failed to evaluate testing personnel TP#2 listed on the CMS Form 209 for Semen analysis. The findings include: 1. Review of 2020, 2021 and 2022 competency assessments revealed no documentation of competency for Semen analysis for TP#2. 2. Interview with TC#1 at 1:30 P.M. on May 11,2022 in the breakroom confirmed the above findings. ==========