Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1044198	04/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Khadijah Jordan, Md, Pc	111 Medical Parkway, 2nd Floor, Chesapeake, 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 CLIA recertification survey was conducted at Khadijah Jordan, MD PC on April 4, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) documentation, and an interview, the laboratory failed to retain documentation of the chemistry analyzer results for two (2) of six (6) PT events reviewed. Findings include: 1. Review of the laboratory's 2016 American Academy of Family Physicians (AAFP) and 2017 American Proficiency Institute (API) PT documentation, a total of six (6) events, revealed no Abbott Architect Plus i1000 instrument result records were retained for: 2016 AAFP Event B: Follicle Stimulating Hormone (FSH), Luteininzing Hormone (LH), Prolactin, Testosterone, Progesterone -PT corrective action report indicated repeat analysis with self grade. No instrument print out records were retained to document the self grade analysis. 2016 AAFP Event C: Follicle Stimulating Hormone (FSH),

	Luteininzing Hormone (LH), Prolactin, Testosterone, Progesterone, Thyroid Stimulating Hormone (TSH), Thyroxine (FT4), Free Triiodothyronine (Free T3), Human Chorionic Gonadotropin (hCG), Dehydroepiandrosterone Sulfate (DHEA-S), Estradiol, Vitamin D. The inspector requested to review the analyzer result print outs for the endocrinology chemistry events listed above. No documentation was available for review. 2. In an interview with the primary testing personnel at approximately 3: 30 PM, it was confirmed that the laboratory failed to retain copies of the Abbott Architect Plus i1000 analyzer result print outs for the PT events outlined above in calendar year 2016.
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 a review of the Laboratory Personnel Report Form (CMS 209), procedure and policy manual, personnel files, and an interview, the laboratory did follow a policy for the technical consultant's competency assessment in calendar year 2017. Findings include: 1. Review of the CMS 209 revealed that Testing Personnel B serves as the Technical Consultant (TC). (See Personnel Code Sheet) 2. Review of the laboratory procedure and policy manual revealed a Quality Assurance protocol outlining documentation of the competency assessment of the laboratory's TC. 3. Review of the personnel files revealed that the laboratory director (LD) failed to complete documentation of the competency assessment for Testing Personnel B in the role of TC in 2017. 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory director did not document the competency assessment for the TC in calendar year 2017.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, PT Corrective Action Forms, and interviews, the laboratory failed to document review of Endocrinology chemistry results for one (1) of six (6) events reviewed. Findings include: 1. Review of the 2016 American Academy of Family Physicians (AAFP) and 2017 American Proficiency Institute (API) PT documentation, a total of six (6) events, revealed no evidence of review of results for: 2016 AAFP Event C. The inspector requested to review the PT documentation. The primary testing personnel stated "our technical consultant reviews the results. I am not sure where the review for Event C is located. We have a new technical consultant now." 2. Review of the laboratory's 2016 PT Corrective Action Forms revealed no corrective or remedial action for failure to document review of results for Follicle Stimulating Hormone (FSH), Luteininzing Hormone (LH), Prolactin, Testosterone, Progesterone, Thyroid Stimulating Hormone (TSH), Thyroxine (FT4), Free Triiodothyronine (Free T3), Human Chorionic Gonadotropin (hCG), Dehydroepiandrosterone Sulfate (DHEA-S), Estradiol, Vitamin

	D. 3. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed document review of results for the proficiency testing event listed above in calendar year 2016.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, package inserts, daily temperature logs, equipment maintenance records, analyzer calibration verification records, and interviews, the laboratory failed to monitor and evaluate analytic quality by: 1. failure to follow manufacturer's storage requirements for endocrinology quality control (see D5413); 2. failure to document laboratory refrigerator, freezer, room, and humidity temperatures (see D5413); 3. failure to follow their written thermometer maintenance protocol (see D5433); 4. failure to perform calibration verification procedures at least once every six (6) months (see D5439).
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: A. Based on a review of policies and procedures, temperature logs, and an interview, the laboratory failed to monitor the laboratory refrigerator, freezer, room, and humidity temperatures according to their written policy in calendar year 2016. Findings include: 1. Review of the General Laboratory Policy and Procedure Manual revealed a General Maintenance policy that states: "record temperatures on a daily basis on the Temperature and General Maintenance Log". The Temperature and General Maintenance Log sheet indicated the following acceptable temperature ranges: Refrigerator - 2-8 Celsius (C), Freezer - less than minus 20 C, Room - 20-30 C, Humidity - 20-80 %. 2. The inspector requested to review the laboratory temperature logs for April 2016 up to the date of survey on 4/4/18. The review of the available temperature records revealed no documentation of refrigerator, freezer, room, or humidity temperatures in calendar year 2016. The inspector requested to review temperature documentation for calendar year 2016. The primary testing personnel stated: "I cannot locate the temperature charts for 2016. We have a new technical consultant. I am not sure how to contact the former consultant to locate the

	records". 3. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to document monitoring of the laboratory refrigerator, freezer, room, and humidity temperatures according to their written policy in calendar year 2016. B. Based on a laboratory tour, review of policies and procedures, package insert, daily temperature logs, and an interview, the laboratory did not follow manufacturer's storage requirements for chemistry endocrinology quality control (QC) material for one hundred ninety-two (192) days of three hundred one (301) days reviewed. Findings include: 1. During a tour of the laboratory at approximately 11:00 AM, the inspector noted one Frigadaire freezer in use for storing patient serum samples and QC material. The inspector noted: Nine (9) unopened bottles of Bio-Rad Liquichek Immunoassay Plus Control (Lot Number 40960). At the time of the lab tour, the Fisher Scientific Digital Thermometer (Serial Number 160161300) read -13 degrees Celsius (C). 2. Review of the General Laboratory Policy and Procedure Manual revealed a General Maintenance policy that stated: "record temperatures on a daily basis on the Temperature and General Maintenance Log". The Temperature and General Maintenance Log sheet indicated the freezer acceptable range as less than minus 20 C. 3. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert revealed a manufacturer's storage and stability requirement that stated: "This product is stable until the expiration date when stored unopened at -20 to -70 degrees Celsius". 4. Review of the daily freezer temperature logs for calendar year 2017 and up to the date of survey on April 4, 2018 revealed that the storage temperature was outside of the manufacturer's requirements of -20 to -70 C on: 1/9/17, 1/10/17, 3/1/17, 3/14/17, 3/23/17, 3/24/17, 3/27/17, 3/28/17, 3/29/17, 4/5/17, 4/11/7, 4/13/17, 4/18/17, 4/19/17, 4/20/17, 4/22/17, 4/24/17, 5/1/17, 5/2/17, 5/5/17, 5/9/17, 5/13/17 through 5/16/17, 5/19/17, 5/23/17, 5/25/17, 5/26/17, 5/30/17, 6/2/17, 6/5/17, 6/12/17 through 6/15/17, 6/19/17, 6/21/17, 6/23/17, 6/26/17, 6/27/17, 6/29/17, 6/30/17, 7/3/17, 7/7/17, 7/10/17, 7/11/17, 7/14/17, 7/19/17, 7/20/17, 7/25/17, 8/1/17, 8/3/17, 8/7/18, 8/8/17, 8/9/17, 8/14/17, 8/15/17, 8/16/17, 8/18/17, 8/21/17 through 8/24/17, 8/29/17, 8/30/17, 9/1/17, 9/7/17, 9/11/17, 9/12/17, 9/15/17, 9/19/17 through 9/22/17, 9/26/17, 9/29/17, 10/2/17 through 10/6/17, 10/12/17, 10/13/17, 10/17/17, 10/19/17, 10/20/17, 10/21/17, 10/23/17, 10/24/17, 10/26/17, 10/27/17, 10/30/17, 10/31/17, 11/1/17, 11/2/17, 11/3/17, 11/6/17 through 11/11/17, 11/14/17, 11/15/17, 11/16/17, 11/20/17, 11/21/17, 12/1/17, 12/4/17 through 12/9/17, 12/12/17 through 12/15/17, 12/19/17, 12/20/17, 12/21/17, 12/26/17 through 12/29/17, 1/2/18, 1/3/18, 1/5/18, 1/6/18, 1/8/18 through 1/12/18, 1/16/18, 1/17/18, 1/19/18, 1/22/18 through 1/27/18, 1/29/18 through 1/31/18, 2/1/18, 2/2/18, 2/5/18 through 2/9/18, 2/12/18, 2/13/18, 2/15/18, 2/16/18, 2/17/18, 2/19/18 through 2/24/18, 2/26/18, 2/27/18, 2/28/18, 3/1/18, 3/2/18, 3/5/18 through 3/9/18, 3/12/18 through 3/16/18, 3/19/18, 3/21/18, 3/22/18, 3/23/18, 3/26/18, 3/28/18 through 3/31/18, 4/2/18 through 4/4/18; a total of one hundred ninety-two (192) days. 5. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory did not follow the Bio-Rad Liquichek Immunoassay Plus Control storage requirements for the QC material used to monitor patient endocrinology testing for one hundred ninety-two (192) days of three hundred one (301) days reviewed in 2017 and up to the date of the survey on 4/4/18.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system

	performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, package inserts, equipment maintenance records, and an interview, the laboratory failed to follow their written maintenance protocol for two (2) of two (2) thermometers located in the main laboratory processing area from January 26, 2018 to the date of the survey. Findings include: 1. During a tour of the laboratory at approximately 11:00 AM, the inspector noted two (2) Fisher Scientific Digital Thermometers in the main lab specimen processing area used to monitor freezer and refrigerator temperatures: Freezer Thermometer - Serial Number (SN) 160161300, Refrigerator Thermometer - SN 11724196. The tour revealed that the laboratory freezer was utilized for storing: Bio-Rad Liquichek Immunoassay Plus Control. The tour revealed that the laboratory refrigerator was utilized for storing the following Abbott Architect Plus i1000 reagents : Follicle Stimulating Hormone (FSH), Luteininzing Hormone (LH), Prolactin, Testosterone, Progesterone, Thyroid Stimulating Hormone (TSH), Thyroxine (FT4), Free Triiodothyronine (Free T3), Human Chorionic Gonadotropin (hCG), Dehydroepiandrosterone Sulfate (DHEA-S), Estradiol, Vitamin D. 2. Review of the General Laboratory Policy and Procedure Manual revealed a General Maintenance Thermometer Check policy that stated: "verify calibration documentation from the manufacturer of each thermometer in use, if manufacturer does not claim lifetime stability, check annually by comparison with a NIST calibration". 3. Review of the thermometer manufacturer's package insert revealed that the factory calibration had a calibration expiration date of 1/26/18. The package insert stated "Digital Humidity and Temperature Meters can be affected by aging, temperature, shock, and contamination". The inspector requested to review maintenance records for confirming the accuracy of the expired thermometer calibrations. No documentation was available for review. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert revealed a manufacturer's storage and stability requirement that stated: "This product is stable until the expiration date when stored unopened at -20 to -70 degrees Celsius (C)". Review of the Abbott Architect Plus i1000 reagent package inserts for FSH, LH, Prolactin, Testosterone, Progesterone, TSH, FT4, Free T3, hCG, DHEA-S, Estradiol, and Vitamin D requirements: "The Architect kits must be stored at 2- 8 C". 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to follow maintenance protocols to confirm the accuracy of two (2) of two (2) digital temperature meters utilized to monitor the storage requirements of the control materials and reagents listed above from January 26, 2018 to the date of the survey, 4/4/18.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, package inserts, analyzer calibration verification records, and an interview, the laboratory failed to perform calibration verification procedures at least once every six (6) months for Endocrinology testing in calendar years 2016 and 2017. Findings include: 1. Review of the General Laboratory Policy and Procedure Manual revealed a Linearity and Calibration Verification policy to perform calibration verification twice a year. The policy states: "analytes with less than three calibration points will be verified twice annually". 2. Review of the Abbott Architect Plus i1000 calibrator package inserts revealed the following five (5) tests with two (2) calibrator points: Free Triiodothyronine (Free T3), Thyroid Stimulating Hormone (TSH), Progesterone, Follicle Stimulating Hormone (FSH), and Prolactin. 3. Review of the laboratory's 2016 and 2017 Architect Plus i1000 calibration verification records revealed calibration verification performance on: 10/31/16 for FT3, TSH, Progesterone, FSH, Prolactin; 10/10/17 for Progesterone. The inspector requested to review additional records. Documentation for additional calibration verification (FT3, TSH, Progesterone, FSH, and Prolactin) in 2016 and (Progesterone, FT3) in 2017 was not available. 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to follow their calibration verification policy for endocrinology testing on the Abbott Architect Plus i1000 analyzer for FT3, TSH, Progesterone, FSH, Prolactin as outlined above in 2016 and 2017. **THIS IS A REPEAT DEFICIENCY**
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on a review of package insert, daily temperature logs, quality assurance

	(QA) action logs, and an interview, the laboratory failed to document corrective measures when the freezer temperatures were outside of manufacturer's storage requirements for endocrinology quality control (QC) material for fifteen (15) of sixteen (16) months reviewed. (Cross reference D5413.) Findings include: 1. The laboratory utilizes Bio-Rad Liquichek Immunoassay Plus Control material to monitor patient endocrinology testing on the Abbott Architect Plus i1000 analyzer. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert revealed a manufacturer's storage and stability requirement that stated: "This product is stable until the expiration date when stored unopened at -20 to -70 degrees Celsius." 2. Review of the daily freezer temperature logs for calendar year 2017 and up to the date of survey on April 4, 2018 revealed that the storage temperature was outside of the manufacturer's requirements of -20 to -70 C on one hundred ninety-two (192) days of three hundred one (301) days reviewed. 3. Review of the laboratory's QA action logs from January 2017 to April 2018 revealed no records of corrective action for the freezer temperature outliers. 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory did not document corrective action when the freezer temperature was outside of the Bio-Rad QC storage requirements during the fifteen (15) of sixteen (16) months reviewed. B. Based on a review of the laboratory's policies and procedures, package inserts, analyzer calibration verification records, quality assurance (QA) action logs, and an interview, the laboratory failed to document corrective measures when calibration verification procedures were not performed at least once every six (6) months for Endocrinology testing in calendar years 2016 and 2017. (Cross reference D5439.) Findings include: 1. Review of the General Laboratory Policy and Procedure Manual revealed a Linearity and Calibration Verification policy to perform calibration verification twice a year. The policy states: "analytes with less than three calibration points will be verified twice annually". 2. Review of the Abbott Architect Plus i1000 calibrator package inserts revealed the following five (5) tests with two (2) calibrator points: Free Triiodothyronine (Free T3), Thyroid Stimulating Hormone (TSH), Progesterone, Follicle Stimulating Hormone (FSH), and Prolactin. 3. Review of the laboratory's 2016 and 2017 Architect Plus i1000 calibration verification records revealed calibration verification studies for FT3, TSH, Progesterone, FSH, and Prolactin testing exceeded six (6) months in calendar year 2016. Progesterone verification exceeded six (6) months in calendar year 2017. FT3 exceeded twelve (12) months in 2017. 4. Review of the laboratory's QA action logs from January 2016 to April 2018 revealed no records of corrective action for the noted timeframes of missed calibration verification documentation. The inspector requested to review corrective action documentation. No records were available. 5. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory did not document corrective action when they failed to follow their calibration verification policy for endocrinology testing on the Abbott Architect Plus i1000 analyzer for FT3, TSH, Progesterone, FSH, Prolactin in 2016 and 2017.
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 a tour of the laboratory, the review of policy and procedures, package inserts, thermometer verification documentation, temperature records, maintenance logs, calibration verification records, quality assurance corrective action documentation, and interviews, the laboratory director failed to ensure that the laboratory's quality management plan addressed and documented corrective actions for issues in the analytic testing phase (Cross Reference D5413, D5433, D5439, D5781).
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 a review of Laboratory Personnel Report form (CMS 209), personnel files, and an interview, the technical consultant failed to assess competency for one (1) of one (1) testing personnel (TP) in calendar year 2017. Findings include: 1. Review of the CMS Form 209 revealed that there is one (1) testing personnel responsible for operating and reporting patient endocrinology results in the Abbott Architect Plus i1000 laboratory room. 2. Review of the laboratory personnel files revealed no 2017 annual competency assessment available for Testing Personnel A. (See Personnel Code Sheet.) The inspector requested to review the competency documentation. The documentation was not available for review. 3. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to document an annual competency assessment for the primary testing personnel as outlined above.