Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0957296	09/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Churchland Internal Medicine	2994 Churchland Boulevard, 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 validation survey was conducted at Churchland Internal Medicine on September 20, 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:
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, Corrective Action Forms, and an interview, the laboratory failed to document evaluation review and remedial verification action taken for chemistry analytes on three (3) out of six (6) PT events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT documentation, a total of six (6) events, revealed no evidence of review evaluation, remedial action, or self grade for the following three (3) proficiency events' analyte challenges: 2018 1st Event: Total Bilirubin 60% Score (Unacceptable score for CH--03, CH-05), Parathyroid Hormone (No score/Not graded for IAT 01, IAT 02, IAT 03), Microalbumin (No score/Not graded for MA-01, MA-02), Whole Blood Glucose 67% Score (Unacceptable Result for WBG-01), 2017 2nd Event: Whole Blood Glucose (No score/Not graded for WBG 06, WBG 07, WBG 08), 2017 1st Event: Whole Blood Glucose (No score/Not graded for WBG 01, WBG 02, WBG 03), Hemoglobin A1c 0% Score (Unacceptable Results for GLY01 and GLY02). 2. Review of the laboratory's API PT Corrective Action forms revealed that the laboratory failed to document review evaluation, corrective/remedial action or self grading for the analyte scores listed above. 3. In an interview with the primary testing personnel at

	approximately 5:00 PM, it was confirmed that the laboratory failed to document review evaluation, remedial or self grade actions for the three (3) of six (6) PT events listed above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of procedures, manufacturer's Operations Manual, instrument maintenance records, and an interview, the laboratory failed to document performance of the TOSOH instrument six (6) month maintenance per the manufacturer's requirements in calendar year 2017. Findings include: 1. Review of the laboratory's procedure manual revealed that the laboratory utilizes a TOSOH A1A chemistry instrument to analyze Ferritin, Prostate Specific Antigen (PSA), Parathyroid Hormone (PTH), Testosterone, Thyroid Stimulating Hormone (TSH), and Thyroxine (FT4) patient results. 2. Review of the TOSOH A1A Operations Manual revealed manufacturer's instructions to: "perform replacement of diluent and waste bottle filters every six months". 3. Review of the laboratory's TOSOH A1A maintenance logs revealed documentation of the six (6) month maintenance on 9/1/17. No additional documentation of replacing the filters in calendar year 2017 was noted. 4. In an interview with the primary testing personnel at approximately 5:00 PM, it was confirmed that the laboratory failed to document performance of the TOSOH A1A filter replacement maintenance per the manufacturer's instructions in calendar year 2017.
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 policies and procedures, calibration verification documentation, a laboratory tour, and interviews, the laboratory failed to perform calibration verification studies for Sodium (Na), Potassium (K), Chloride (CL), Hemoglobin A1C (HbA1c), Ferritin, and Prostate Specific Antigen (PSA) chemistry assay tests according to the laboratory's written policy from August 2016 to July 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a quality assurance (QA) policy to perform calibration verification for the following Vitros 250, TOSOH G8, and TOSOH A1A chemistry analyzer tests: Na, K, CL, HbA1c, Ferritin, and PSA. The policy stated: "Calibration validation linearity studies are performed at least every six months for these assay tests that have only two points of calibration." 2. Review of the laboratory's calibration verification documentation revealed no calibration verification in calendar year 2017 for: Vitros 250 test assays Na, K, CL, TOSOH G8 test assay HbA1c, TOSOH A1A test assays Ferritin, PSA. The inspector requested to review documentation of calibration verification performed in calendar year 2017 for the test assays outlined above . The documentation was not available for review. 3. During a laboratory tour at approximately 1:30 PM, the inspector asked the primary testing personnel to describe how the calibration verification policy is followed. The primary testing personnel stated: "It is the policy to run the verification studies every 6 months for the tests with two point calibration curves but I am unable to find the documentation that they were performed twice in 2017. I can locate the studies performed in February 2016 and in July 2018". The laboratory tour and interview confirmed a twenty-three (23) month lapse in calibration verification procedures for Na, K, CL, HbA1c, Ferritin, and PSA. 4. In an interview with the primary testing personnel and lab director at approximately 4:45 PM, it was confirmed that the laboratory failed to document performance of calibration verification according to their written QA policy for the six (6) test assays outlined above for twenty-three (23) of the twenty-four (24) months reviewed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) records, laboratory tour, and an interview, the laboratory failed to perform an evaluation of statistical analysis to identify possible shifts and trends for the complete blood count (CBC) Coulter AcT Diff Plus QC materials for six (6) of twenty-four (24) months reviewed. Findings include: 1. Review of the 2017 and 2018 QC records for the Beckman Coulter AcT

	Diff hematology instrument's AcT Diff Plus QC materials revealed that the laboratory did not have documentation of performing a statistical review or analysis from January 2018 to June 2018. The inspector requested to review the QC statistical review documentation. No documentation was available. 2. During a laboratory tour of the hematology testing area at approximately 3:30 PM, the inspector asked the primary testing personnel to describe how the laboratory identifies shifts and trends for the AcT Diff Plus QC materials. The primary testing personnel stated: "The lab submits the QC data to Beckman's online peer review. It is printed out to review each month. We had a staffing shortage and it was over looked in the first of this year." 3. In an interview with the primary testing personnel and lab director at approximately 4: 45 PM, it was confirmed that the laboratory failed to document an evaluation analysis to identify possible shifts and trends of the CBC QC materials for a six (6) month timeframe, outlined above, in calendar year 2018.
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 review of the proficiency testing records, corrective action forms, instrument maintenance logs, manufacturer's Operation Manual, policies and procedures, maintenance logs, hematology quality control (QC) records, and an interview, the laboratory director failed to ensure that the quality assurance (QA) policies were established and maintained during the twenty-four (24) months of September 2016 to the date of the survey on September 20, 2018. Findings include: 1. The laboratory director failed to establish a QA program that included: -document review and remedial action for unacceptable or non-graded chemistry analytes. (Cross Reference D 5221.) -a review to ensure documentation of TOSOH A1A six (6) month preventative maintenance per the manufacturer's requirement. (Cross Reference D 5429.) -evaluation and documentation of statistical review analysis to identify possible shifts and trends for the CBC Coulter AcT Diff Plus QC materials. (Cross Reference D 5469.) 2. The laboratory director failed to maintain the QA policy that included documentation of calibration verification studies for Sodium (Na), Potassium (K), Chloride (CL), Hemoglobin A1C (HbA1c) , Ferritin, and Prostate Specific Antigen (PSA) chemistry assay. (Cross Reference D 5439.) 3. In an interview with the primary testing personnel and lab director at approximately 4:45 PM, it was confirmed that the laboratory director failed to establish and maintain a QA policy that included the items listed above.
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 Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document initial training competency for one (1) of six (6) testing personnel in 2018. Findings include: 1. Review of the CMS Form 209 revealed that the laboratory director also performs the duties of TC and that there are six (6) testing personnel (TP). Review of the form with the primary testing personnel revealed that TP F performed patient testing in 2018 as a new staff member. (See attached Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed no initial training or competency assessments available for TP F. The inspector requested to review additional training and competency documentation. The documentation was not available for review. 3. In an interview with the primary testing personnel at approximately 5:00 PM, it was confirmed that the TC failed to perform an initial training competency evaluation for TP F.
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to perform annual competency evaluations for two (2) of six (6) testing personnel (TP) in 2016 and three (3) of six (6) TP in 2017. Findings include: 1. Review of the CMS Form 209 revealed that the laboratory director also performs the duties of TC and that there are six (6) testing personnel (TP). 2. Review of the laboratory personnel files revealed the following: TP B - Competency Assessment in 2017 was performed by TP B, TP C - Competency Assessment in 2016 and 2017 not documented, TP D - Competency Assessment in 2016 and 2017 not documented. (See attached Personnel Code Sheet.) 3. In an interview with the primary testing personnel at approximately 5:00 PM, it was confirmed that the TC failed to perform annual competency evaluations for the three (3) testing personnel as outlined above.