Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0961491	02/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Chickahominy Family Practice- Central Lab	9010 Pocahontas Trail, Providence Forge, 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 Chickahominy Family Practice-Central Lab on February 22-23, 2024 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 and include the Condition under 42 CFR part 493 CLIA Regulation: D6000 -42 CFR. 493.1403 Laboratory Director.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for nine (9) analytes in one out of three 2023 Chemistry testing events. Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute (API) Core Chemistry PT records (Events 1, 2, and 3) revealed unsatisfactory performance scores (less than 80%) for the following 9 analytes on the API 2023 3rd Event: Albumin - 60% (CH-14 resulted as 3.9 outside acceptable range of 2.9-3.7, CH-15 resulted as 3.5 outside acceptable range 2.6-3.3); AST/GOT - 60% (CH-14 resulted as 220 outside acceptable range of 138-208, CH-15 resulted as 179 outside acceptable range 112-170); Calcium, Total - 60% (CH-14 resulted as 12.4 outside acceptable range of 9.2-11.3, CH-15 resulted as 11.8 outside acceptable range 8.5-10.6); Creatinine - 60% (CH-14 resulted as 3.75 outside acceptable range of 2.64-3.58, CH-15 resulted as 3.11 outside acceptable range 2.2-2.98); Ferritin - 50% (IA-12 resulted as 9 outside acceptable range 134-167); Glucose - 60% (CH-14 resulted as 187 outside acceptable range of 144-177, CH-15 resulted as 162 outside acceptable range 123-152); LDL Cholesterol, Direct - 60% (CH-12 resulted as 17 outside acceptable range of 28-37,

	CH-15 resulted as 51 outside acceptable range 40-50); Phosphorus - 60% (CH-14 resulted as 5.2 outside acceptable range of 4.1-4.6, CH-15 resulted as 4.6 outside acceptable range 3.6-4.1); Urea Nitrogen - 60% (CH-14 resulted as 34 outside acceptable range of 25-31, CH-15 resulted as 189 outside acceptable range 117-196). 2. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Parathyroid Hormone (PTH) and Prostate Specific Antigen (PSA) analytes in one out of three 2023 chemistry endocrinology module events. Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute (API) PT records (Events 1, 2, and 3) revealed that the laboratory utilized API for accuracy verification for PTH and PSA patient testing. The inspector noted the following unacceptable PTH and PSA scores (less than 80%) on the API 2023 3rd Event: PTH scored 50% (challenge sample IAS-12 resulted as 18.4 outside acceptable range of 141.1-182.8), PSA scored 50% (challenge sample IA-11 resulted as 140.00 outside acceptable range of 7.51-11.08). 2. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D report form (CMS CASPER 96), proficiency testing (PT) records and an interview, the laboratory failed to attain an overall score of at least eighty percent (80%) of acceptable responses for the specialty of Endocrinology in one out of two module events reviewed for calendar year 2022. Findings include: 1. During pre-survey duties, the inspector noted that the CMS CASPER 96 report included an overall unsatisfactory PT score for the specialty of Endocrinology. The pre-survey review revealed the laboratory received 60 % score for 2022 Event 3. 2. During the onsite inspection on 2/22/24, the inspector reviewed of the laboratory's 2022 American Proficiency Institute (API) PT Events 2 and 3. The review revealed unsatisfactory scores on the API 2022 3rd Event: Endocrinology speciality overall scored at 60% - module specific Thyroid Stimulating Hormone scored 60%, (challenge sample CH-12 resulted as 2.27 outside acceptable range of 1.20-2.16, challenge CH-13 resulted as 4.38 outside acceptable range of 2.29-4.18). 3. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.

D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on tour, review of procedures, lack of documentation, quality assessment (QA) check lists, and interviews, the laboratory failed to document eye wash safety /maintenance per their protocol for forty (40) of ninety-two (92) weeks reviewed (April 2022 to February 23, 2024). Findings include: 1. During a tour of the laboratory on 2/22/24 at 10:00 AM, the inspector noted one safety eye wash in the chemistry laboratory entrance area. 2. Review of the laboratory's procedures revealed a protocol (titled: Quality Assessment) with subheading "Temperature, Humidity Monitoring, and Eyewash Maintenance" that stated: "The faucet mounted eyewash station will be tested each Monday and allowed to flush for 30-60 seconds. This testing will be documented on log." 3. Review of the available eyewash maintenance logs for timeframe of April 2022 to 2/23/24 revealed no documentation of weekly safety checks in the following months: Calendar year 2023: January (5 weeks), February (4 weeks), March (4 weeks), April (4 weeks), May (5 weeks), June (4 weeks), July (4 weeks), and August (5 weeks); Calendar year 2024: January (5 weeks). A total of 40 weeks during the nine months outlined above had no weekly eye wash safety checks recorded. 4. A review of monthly QA report/checklists for the timeframe outlined above revealed no corrective action documented regarding the lack of weekly eyewash checks. 5. An exit interview with the laboratory lead on 2/23 /24 at 12:30 PM confirmed the above findings.
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 proficiency testing (PT) records, procedures, lack of documentation, and interview, the laboratory failed to record an evaluation of nine (9) unacceptable chemistry challenge scores reported on four (4) of five (5) PT events reviewed per their policy (timeframe April 2022 to the date of the inspection February 22-23, 2024). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records (2022 Events 2-3, 2023 Events 1-3), a total of 5 events, revealed no evidence of evaluation for each of the following failed analyte challenge samples reported as unacceptable: 2022 API Event 2: Carbon Dioxide (challenge CH-06); 2023 API Event 1: Sodium (challenge CH-03); 2023 API Event 2: LDL Cholesterol Direct (challenge CH-08); 2023 API Event 3: AST/SGOT (challenges CH-14, CH-15), Creatinine (challenge CH-14), Phosphorus (challenge CH-14), Urea Nitrogen (challenges CH-14, CH-15); A total of 4 out of 5 events reviewed had unacceptable analyte results reported with no evaluation/corrective action noted. 2. Review of the laboratory's procedures revealed a policy (title: Proficiency Testing) that stated, "The Lab Director and/or his designee will review all proficiency test results and all corrective actions for unacceptable results. All unacceptable results must be reviewed and investigated. This will be overseen by the Technical Consultant

	and/or Lab Director" The inspector requested to review documentation that the laboratory evaluated the unacceptable challenge results outlined above. Documentation was not available for review. 3. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.
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: A. Based on a review of analyzer maintenance logs, manufacturer's operator manual, quality assurance (QA) logs, lack of documentation, and an interview, the laboratory failed to document performance of every six (6) month Tosoh G8 chemistry analyzer maintenance as required in calendar years 2022 and 2023. Findings include: 1. Review of the laboratory's Tosoh Bioscience G8 chemistry analyzer maintenance logs revealed the following preventative maintenance procedure outlined to be performed every 6 months: Suction Filter Replacement. The inspector noted one entry of documentation dated 4/4/23 during the 23 months of review (timeframe of March 10, 2022 to February 23, 2024). 2. Review of the G8 operator's manual revealed semi-annual maintenance instructions that stated: "The inlet end of the buffer tube houses suction filters. Replace all three filters at the same time and then prime for elution buffer 1, 2, 3. Perform every 6 months." 3. The inspector requested to review additional documentation that the semi-annual G8 maintenance procedure outlined above was performed in calendar years 2022 and 2023. No records were available. 4. A review of monthly QA report/checklists for the timeframe outlined above revealed no corrective action documented regarding the lack of semi-annual maintenance records. 5. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings B. Based on a review of Tosoh A1A 900 chemistry analyzer maintenance records, manufacturer's operator manual, quality assurance (QA) logs, lack of documentation, and an interview, the laboratory failed to document performance of required A1A 900 weekly maintenance for twenty (20) of ninety-two (92) weeks reviewed (April 2022 to February 23, 2024). Findings include: 1. Review of the Tosoh A1A 900 maintenance logs revealed two preventative maintenance procedures (Clean B/F Wash Probe Tip and Clean Substrate Line with 70% Ethanol 5 times) outlined to perform on a weekly basis. The inspector noted the two maintenance protocols were not documented as performed on the following weeks during the review timeframe of April 2022 to 2/23/24: Calendar year 2022: weeks of 06/20/22, 07/18/22, 11/01/22, 11/07/22; Calendar year 2023: weeks of 03/06/23, 03/13 /23, 03/20/23, 03/27/23, 05/1/23, 05/8/23, 05/15/23, 05/22/23, 05/30/23, 06/05/23, 06 /26/23, 11/06/23, 12/04/23, 12/18/23, 12/27/23; Year to date 2024: week 01/08/24; A total of 20 weeks lacked documentation that the required weekly A1A 900 maintenance was performed. 2. Review of the A1A 900 operator's manual revealed manufacturer's instructions (under heading Weekly Maintenance) "Wash the inside of the Substrate tube at the end of assays once a week to ensure that the substrate background intensity does not rise. Replace the substrate bottle with 70% Ethanol solution and select Replace Substrate at interval 5 so that the substrate replacement will be repeated 5 times. Clean the probe tip after the end of assays once a week to ensure accuracy/precision at low concentrations are not affected. Note: if the probe tip is very dirty -it should be pulled out and an ultrasonic cleaning for 5 minutes with

	neutral detergent and CAP Class I or NCCLS Type 1 Reagent Grade water." 3. The inspector requested to review documentation that the A1A 900 weekly protocols were performed during the 20 weeks outlined above. No records were available. 4. A review of monthly QA report/checklists for the timeframe outlined above revealed no corrective action documented regarding the lack of weekly maintenance noted above. 5. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings. C. Based on a review of Siemens Dimension XPand chemistry analyzer maintenance logs, manufacturer's operator manual, quality assurance (QA) logs, lack of documentation, and an interview, the laboratory failed to document weekly XPand maintenance for sixty-four (64) of ninety-two (92) weeks reviewed (timeframe of April 2022 to February 23, 2024). Findings include: 1. Review of the Dimension XPand maintenance logs revealed two maintenance procedures (Clean Outside of R2 Probe, Clean HM Wash Probe) to perform on a weekly basis. The inspector noted no documentation that the protocols were followed during the following weeks of the review timeframe April 2022 to 2/23/24: Calendar year 2022: weeks of 05/09/22, 05/16/22, 05/23/22, 05/30/22, 06/13/22, 06/20/22, 06/27/22, 07/11/22, 07/18/22, 07/25/22, 08/15/22, 08/22/22, 08/29/22, 10/10/22, 10/17/22, 11/1/22, 11/07/22, 11/14/22, 11/21/22, 11/28/22; Calendar year 2023: weeks of 01/9/23, 01/16/23, 01/23/23, 01/30/23, 02/13/23, 02/20/23, 02/27/23, 03/13/23, 03/20/23, 03/27/23, 04/10/23, 04/17/23, 04/24/23, 05/01/23, 05/08/23, 05/15/23, 05/22/23, 05/30/23, 06/05/23, 06/26/23, 07/17/23, 07/24/23, 7/31/23, 08/07/23, 08/14/23, 08/21/23, 08/28/23, 09/11/23, 09/18/23, 09/25/23, 10/09/23, 10/16/23, 10/23/23, 10/30/23, 11/13/23, 11/20/23, 12/04/23, 12/11/23, 12/18/23, 12/27/23; Year to date 2024: weeks of 01/08/24, 01/15/24, 01/22/24, 01/29/24; A total of 64 weeks lacked documentation that the required weekly XPand maintenance was performed. 2. Review of the Dimension XPand operator's guide revealed manufacturer's instructions (under heading Weekly Maintenance) - "Clean the HM Wash Probes and R2 Reagent Probe - to ensure residue is removed." 3. The inspector requested to review documentation that the XPand weekly protocols were performed during the 64 weeks outlined above. No records were available. 4. A review of monthly QA report/checklists for the timeframe outlined above revealed no corrective action documented regarding the lack of weekly maintenance noted above. 5. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of procedures, proficiency testing (PT) records, tour, maintenance logs, manufacturer's operations manuals, lack of documentation, and interview, the laboratory director failed to ensure: 1. quality assurance protocols for PT corrective action were documented when the laboratory's overall score Endocrinology speciality was reported as unsatisfactory in one out of two module events reviewed for calendar year 2022 - CROSS REFERENCE D6019 A; 2. quality assurance protocols for PT corrective action were followed on four of five PT chemistry events reviewed in the timeframe of April 2022 to the date of the inspection February 22-23, 2024 - CROSS REFERENCE D6019 B; 3. adherence to eyewash safety check protocols and manufacturer's preventative maintenance schedules for three (3) of 3 chemistry

	analyzers in the survey timeframe of 3/10/22 to 2/23/24 - CROSS REFERENCE D6022.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: A. Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D report form (CMS CASPER 96), proficiency testing (PT) records, procedures, lack of documentation, and interview, the laboratory director (LD) failed to ensure that quality assurance protocols for PT corrective action were documented when the laboratory's overall score Endocrinology speciality was reported as unsatisfactory in one out of two module events reviewed for calendar year 2022. CROSS REFERENCE D2099. Findings: 1. During pre-survey duties, the inspector noted that the CMS CASPER 96 report included an overall unsatisfactory PT score for the specialty of Endocrinology. The pre-survey review revealed the laboratory received 60 % score for 2022 Event 3. 2. During the onsite inspection on 2/22/24, the inspector reviewed of the laboratory's 2022 American Proficiency Institute (API) PT Events 2 and 3. The review revealed unsatisfactory scores on the API 2022 3rd Event-Endocrinology speciality overall was scored at 60%. The inspector noted that the laboratory recorded a recalibration of TSH assay upon receipt of the unsatisfactory results. The inspector inquired regarding an assessment/patient result review for the timeframe of the the accuracy shift. No documentation was available. 3. Review of the laboratory's procedures revealed a Quality Assessment policy that outlined under sub title Proficiency Testing- "The laboratory must evaluate for effectiveness the corrective action taken for unacceptable and unsatisfactory performance". 4. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings. B. Based on a review of procedures, proficiency testing (PT) records, lack of documentation, and interview, the LD failed to ensure that quality assurance protocols for PT corrective action were followed per policy on four (4) of five (5) PT events reviewed (timeframe April 2022 to the date of the inspection February 22-23, 2024). CROSS REFERENCE D5221. 1. Review of the laboratory's American Proficiency Institute (API) PT records (2022 Events 2-3, 2023 Events 1-3), a total of 5 events, revealed no evidence of evaluation for each of the following analyte challenge samples reported as unacceptable on 4 events: 2022 API Event 2: Carbon Dioxide (challenge CH-06); 2023 API Event 1: Sodium (challenge CH-03); 2023 API Event 2: LDL Cholesterol Direct (challenge CH-08); 2023 API Event 3: AST/SGOT (challenges CH-14, CH-15), Creatinine (challenge CH-14), Phosphorus (challenge CH-14), Urea Nitrogen (challenges CH-14, CH-15). 2. Review of procedures revealed a Proficiency Testing policy that stated, "The Lab Director and/or his designee will review all proficiency test results and all corrective actions for unacceptable results. All unacceptable results must be reviewed and investigated. This will be overseen by the Technical Consultant and/or Lab Director". The inspector requested to review

	documentation that the laboratory evaluated the unacceptable challenge results outlined above. Documentation was not available for review. 3. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, maintenance logs, manufacturers' operator manuals, lack of documentation, and interview, the laboratory director failed to identify quality assessment (QA) failures on monthly QA checklists when: 1. safety eyewash inspection/testing/flushing tests did not adhere to QA protocols for forty of ninety-two (92) weeks reviewed (April 2022 to February 23, 2024) - Cross Reference D3011; 2. scheduled every six month preventative maintenance was not performed per manufacturer's instructions and chemistry log protocol for the Tosoh G8 Chemistry analyzer in calendar years 2022 and 2023 - Cross Reference D5429 A; 3. scheduled weekly preventative maintenance was not performed per manufacturer's instructions and chemistry log protocol for the Tosoh A1A 900 Chemistry analyzer for twenty of 92 weeks reviewed (April 2022 to 2/23/24) - Cross Reference D5429 B; 4. scheduled weekly maintenance was not performed per manufacturer's instructions and chemistry log protocol for the Siemens Dimension XPand Chemistry analyzer for sixty-four of 92 weeks reviewed (April 2022 to 2/23/24) - Cross Reference D5429 C.
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 records, lack of documentation, and an interview, the technical consultant (TC) failed to perform annual chemistry competency evaluations for testing personnel A (TP A) for one of two years reviewed (review timeframe March 10, 2022 to dates of inspection February 22-23, 2024). *See Personnel Code Sheet. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performed the duties of TC and had identified TP A as responsible for moderate complexity testing on Tosoh Bioscience G8 Variant, Tosoh A1A 900, and Siemens Dimension XPand clinical chemistry system analyzers during the review timeframe of 3/10/22 to 2/23 /24. 2. Review of the laboratory personnel files for the timeframe outlined above revealed no chemistry competency evaluations for TP A in calendar year 2023. The inspector noted that the LD documented competency assessment performed on 1/9/24.

	The inspector requested to review annual competency assessments for the moderate complexity chemistry testing performed by TP A during calendar year 2023. No documentation was available for review. 3. An exit interview with the laboratory lead on 2/23/24 at 12:30 PM confirmed the above findings.