Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2159558	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Veracyte Labs Va	737 N 5th Street Suite 600, Richmond, 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 initial survey was conducted at Haliodx on May 21st and 22nd, 2019 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:
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: Based on a review of polices, maintenance logs, field service engineer reports, patient test log, and interviews, the laboratory did not follow manufacturer's maintenance requirements for the Elga Purelab Ultra water purification system from April 26, 2019 to May 21, 2019 while processing and reporting one (1) immunoscore patient result during the lapse of maintenance. Findings include: 1. Review of the laboratory's Standard Operating Procedures (SOP) manual revealed a policy (title "Metrology and Preventative Maintenance of Distilled Water System, PCL03-004 V01) that included a manufacturer's maintenance chart that outlined replacement of POU Filter, LC182 Labpure S1, LC183 Labpure S1, LC184 Labpure S3, LC185 Labpure S4, and LC109 Ultra Micro Filter at a required frequency of every six (6) months. 2. Review of the available maintenance logs revealed the date of the water system installation as 10/26 /18. No record of 6 month filter replacement was recorded (review timeframe: October 2018 to the date of the survey on 5/21/19). The inspector requested to review

	documentation of the filter replacements for the six month timeframe at 4/26/19. No records were available. The technical consultant (TS) stated, at approximately 3 PM on 5/21/19, "We did not realize that we could perform the six month filter replacements and called to request field service this week. He came in this morning and performed a preventative maintenance check." 3. Review of the Elga Purelab Ultra field service maintenance reports revealed a report (Report Number EB052119-1) dated 5/21/19 by an Elga service provider engineer that stated, "When I arrived the final quality reading was bad. I confirmed with handheld that conductivity reading was 18.2 and replaced the line cell; rotated LC182." 4. Review of the immunoscore patient test logs revealed 1 patient (identifier number 20920030) was processed on 5 /13/19 during the one month lapse of the required filter replacement maintenance. 5. In an interview with the quality manager, TS, and laboratory owner at approximately 12:00 PM on 5/22/19, the above listed findings were confirmed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of procedures, manufacturer's package insert, validation records, and interviews, the laboratory failed to ensure that sixteen (16) packages of Roche Hematoxylin II stain, stored in the laboratory for use, were within the manufacturer's stated expiration dates. Findings include: 1. During a laboratory tour, at approximately 4:00 PM on 5/21/19, the inspector noted that 16 packages of Roche Ventana Hematoxylin II stain (Lot Number Y05952) had written receive dates of 11/30/18 and manufacturer stamped expiration dates of 4/18/19. The inspector opened two (2) of the 16 unopened packages and noted areas of stain precipitation in the containers. The laboratory inspector inquired if the the stain was currently used for patient testing. The general supervisor (GS) stated, "We used that lot number of stain for our validation and patient testing up to the expiration date and have not discarded it yet". The technical supervisor (TS) stated, "We plan to validate the use of the Ventana stain reagent kits beyond the expiration dates for experimental purposes." 2. Review of the laboratory's Standard Operating Procedures (SOP) manual revealed a policy (titled "Inventory Control for CLIA US Lab" Policy PCL08-003 R 02) that stated "All reagents must be stored according to manufacturer's recommendations (temperature, flammable, or reactivity restrictions) and all expired reagents must be discarded." 3. Review of the Roche Ventana Medical Systems Hematoxylin II stain package insert revealed storage and handling instructions that stated, "Do not use the reagent beyond the expiration date. The signs indicating instability of this product are precipitation of the reagent with clearing of the solution. At the first sign of instability of the reagent, contact Ventana."" 4. Review of the laboratory's validation study records revealed no quality plan validating use of Ventana Hematoxylin II reagent beyond the manufacturer's stated expiration dates. The inspector requested to review the validation of reagent use beyond expiration date. No record was available for review. 5. In an interview with the quality manager, TS, and laboratory owner at approximately 12:00 PM on 5/22/19, the above listed findings were confirmed.