Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1002070	02/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Skin Center Of Northern Virginia, The	3700 Joseph Siewick Drive - Suite 404, Fairfax, 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 Clinical Skin Center of Northern Virginia on February 1, 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's immunology proficiency testing (PT) records, Hitachi CLA-1 analyzer documentation, and interviews, the laboratory failed to rotate proficiency testing among personnel performing patient immunology testing in 2016 and 2017. Findings include: 1. Review of the laboratory's 2015, 2016, and 2017 American Proficiency Institute (API) immunology PT documentation revealed that the laboratory is enrolled as customer number 69032 and that testing personnel A performed seven (7) of seven (7) events reviewed. (See Personnel Code Sheet) 2. Review of the laboratory's Hitachi CLA-1 Luminometer Allergen Specific IgE analyzer documentation revealed that testing personnel (TP) A and B received initial training from the manufacturer's field service engineer in calendar year 2015 as operators and that patient data logs, quality control runs, and calibration verification studies were performed by both TP A and B in 2016 and 2017. 3. During a facility tour at approximately 2:30 PM, the inspector interviewed the laboratory director regarding the testing personnel who utilize, operate, and report results from the Hitachi CLA-1 analyzer. The laboratory director stated that "TP A is the primary testing personnel and TP B is our back up operator". 4. In an exit interview with the laboratory director, clinical consultant, office manager, and primary testing personnel

	on 2/1/18 at approximately 4:30 PM , it was confirmed that the laboratory failed to rotate immunology proficiency testing among all personnel responsible for performing patient testing on the Hitachi CLA-1 assay in 2016 and 2017.
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 laboratory's 2015, 2016, and 2017 immunology proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director and testing personnel for three (3) of seven (7) events reviewed and failed to retain documentation of the analyzer results for seven (7) of seven (7) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) immunology PT documentation (customer number 69032), a total of seven (7) events, revealed no signed attestation statements for: 2017 Event 1 2017 Event 2 2017 Event 3 and revealed no Hitachi CLA-1 Luminometer instrument result print outs were retained for: 2015 Event 3 2016 Event 1 2016 Event 2 2016 Event 3 2017 Event 1 2017 Event 2 2017 Event 3. The inspector requested to review the attestation documentation and analyzer result print outs for the immunology events listed above. No documentation was available for review. 2. In an exit interview with the laboratory director, clinical consultant, office manager, and primary testing personnel on 2/1/18 at approximately 4:30 PM , it was confirmed that the laboratory failed to retain copies of the API attestation statements and the Hitachi CLA-1 analyzer result print outs for the PT events outlined above in 2015, 2016 and 2017.
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 facility tour, review of manufacturer's package insert, analyzer patient report documentation, and interviews, the laboratory failed to ensure that the immunology test reagents were within the manufacturer's expiration dates prior to reporting twelve (12) patient allergen panel results on 11/16/17. Findings include: 1. During a facility tour at approximately 2:30 PM on 2/1/18, which included the immunology specimen processing area, the inspector noted one (1) box of Hitachi

	CLA Allergen Test Reagent (Lot Number 47A06639), expiration date of 10/31/17, stored in the refrigerator. The test kit had six (6) of twenty (20) tests remaining for use. The primary testing personnel stated, "I need to pull that out and dispose of it". 2. Review of the Hitachi CLA reagent manufacturer's package insert revealed storage instructions to "Store kit components at 2-8 degrees Celsius. When stored as directed, the kit components can be used until the printed expiration date". 3. Review of the laboratory's Hitachi CLA-1 analyzer patient report documentation from January 2017 to the date of the survey, revealed that CLA Allergen Test Reagent kit (Lot Number 47A06639, expiration date of 10/31/17) was utilized on 11/16/17 to report: Cassette A : Patient Slot 3 Cassette A : Patient Slot 4 Cassette A : Patient Slot 5 Cassette B : Patient Slot 1 Cassette B : Patient Slot 2 Cassette B : Patient Slot 3 Cassette B : Patient Slot 4 Cassette B : Patient Slot 5 Cassette A2: Patient Slot 1 Cassette A2: Patient Slot 2 Cassette A2: Patient Slot 3 Cassette A2: Patient Slot 4 a total of twelve (12) patient allergen panel results. 4. In an exit interview with the laboratory director, clinical consultant, office manager, and primary testing personnel on 2/1/18 at approximately 4:30 PM, it was confirmed that the laboratory failed to ensure that the CLA Allergen Test Reagent kit reagents were not used beyond the manufacturer's expiration dates prior to reporting the twelve (12) patient results identified above on 11 /16/17.
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 facility tour, review of manufacturer's package inserts, maintenance records, patient logs, and an interview, the laboratory failed to establish maintenance protocols for two (2) of two (2) thermometers located in the immunology specimen processing area used to monitor Hitachi CLA IgE Assay reagent and patient sample storage. Findings include: 1. During a facility tour of the immunology specimen processing area on 2/1/18 at approximately 2:30 PM, the inspector noted a Thomas Scientific Thermometer Serial Number 150561211 with a manufacturer's calibration expiration date of 7/24/17 in the refrigerator. The digital thermometer was in use to monitor the following Hitachi reagents stored in the refrigerator: CLA IgE Assay Allergen Test Chambers CLA IgE Assay Wash Buffer Concentrate CLA IgE Assay IgE Antibody Solution CLA IgE Assay Photoreagent A CLA IgE Assay Photoreagent B CLA IgE Assay Photoreagent C CLA IgE Assay Photoreagent D During the tour, the inspector also noted a Thomas Scientific Thermometer Serial Number 112003272 with a manufacturer's calibration expiration date of 12/27/13 in the laboratory's freezer in use to monitor approximately 20 (twenty) patient specimens and two (2) CLA IgE Positive and Negative Control Serum vials. 2. Review of the two Thomas Scientific meters' manufacturer's package inserts revealed the statement "Digital Humidity and Temperature Meters can be affected by aging, temperature, shock, and contamination." 3. Review of the laboratory's equipment maintenance records from October 2015 to the date of the survey, revealed no calibration documentation for

	thermometer Serial Number 150561211 or Serial Number 112003272. The inspector requested to review written maintenance protocols for confirming the accuracy of the expired thermometers calibrations. No documentation was available for review. 4. Review of the laboratory's Hitachi CLA IgE Assay patient log sheets from October 2015 to the date of the survey on 2/1/18 revealed: 2015: 1476 patient allergen tests were resulted (41 patients; 36 panels each) 2016: 4320 patient allergen tests were resulted (120 patients; 36 panels each) 2017 to date of the survey: 2844 patient allergen tests were resulted (79 patients; 36 panels each) 5. In an interview with the laboratory director, clinical consultant, office manager, and primary testing personnel on 2/1/18 at approximately 4:30 PM, it was confirmed that the laboratory failed to establish and follow maintenance protocols to confirm the accuracy of two (2) of two (2) digital thermometers utilized to monitor the storage requirements of the Hitachi CLA IgE Assay reagents and patient samples while reporting two hundred forty (240) patient panels from October 2015 up to the date of the survey on 2/1/18.
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 the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interviews, the technical consultant failed to assess Hitachi CLA-immunology testing competency for two (2) of two (2) testing personnel in 2016 and 2017. Findings include: 1. Review of the CMS Form 209: Laboratory Personnel Report revealed that there are seven (7) testing personnel (TP) and that the laboratory director also performs the duties of technical consultant. 2. During a facility tour at approximately 2:30 PM, the inspector asked which testing personnel utilize, operate, and report results from the Hitachi CLA-1 analyzer. The laboratory director stated "TP A is the primary testing personnel and TP B is our back up operator". (See Personnel Code Sheet) 3. Review of the laboratory personnel files revealed no Hitachi CLA-1 competency assessments in calendar year 2016 or 2017 for: Testing Personnel A, Testing Personnel B. The inspector requested to review the TP competency documentation. The documentation was not available for review. 4. In an interview with the laboratory director, clinical consultant, office manager, and primary testing personnel on 2/1/18 at approximately 4:30 PM it was confirmed that the laboratory failed to document immunology Hitachi CLA-1 analyzer competency assessments for two (2) of two (2) TP in 2016 and 2017.