Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2159797	02/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Johns Hopkins Imaging At Green Spring Station	10803 Falls Road Suite 1100, Lutherville, MD	

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
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 review of the laboratory records and interview with the technical consultant, the laboratory did not ensure that reagent strips and quality control (QC) materials used in the laboratory were not used after their expiration date. Findings: 1. The laboratory's reagent strips and QC records from June 2019 through January 2020 were reviewed. The laboratory records show the validation of each new lot prior to being used by the laboratory. 2. The manufacturer states that once you open the reagent strips they are good for 90 days and the QC materials are good for 5 weeks. The laboratory documents the opened date and discard date on the containers. Once the laboratory uses the contents of the reagent strips and QC materials the container is discarded along with the documentation on the container. 3. The laboratory records do not include the documentation of the opened date and discard date on the containers to show that they were not used past the new expiration date. 4. During the survey on 02 /05/2020 at 11:30 AM the testing person confirmed that the laboratory records did not include documentation of the opened date and discard date on the containers to show that they were not used past the new expiration date.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient's final reports and interview with the technical consultant, the laboratory did not ensure that the final test report listed the name and address of the testing location which is listed on the CLIA certificate. Findings: 1. The laboratory moved to its current location in June 2019. During the survey three electronic patient charts were pulled for review. Review of the patients results showed that the name listed on the final reports was "Johns Hopkins Medical Lab" and the address was not the location that was being surveyed. 2. The technical consultant explained that the laboratory shares the computer system with 15 other imaging laboratories and the information technology staff were aware of the issue of the final reports not having the correct name and address. 3. During the exit interview on 02/05/2020 at 11:30 AM the technical consultant confirmed that the final reports in the shared computer system did not include the correct name of the laboratory performing the tests for each of the 15 imaging laboratories.