

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D2181931	<b>(X3) Date Survey Completed</b> 05/05/2020
<b>Name of Provider or Supplier</b> Arcpoint Labs Of Rock Hill	<b>Street Address, City, State</b> 725 Cherry Road, Rock Hill, SC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and testing personnel interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for the Coronachek COVID-19 IgG/IgM test for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) (See D5209, D5291)</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation and testing personnel interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the testing personnel who performed the Coronachek COVID-19 IgG/ IgM test. Findings include: 1. During the onsite complaint investigation on 05/05/2020, the laboratory failed to provide written policies and</p>

	<p>procedures to detail how the laboratory would assess the competency of the testing personnel conducting the Coronacheck COVID-19 IgG/ IgM test. 2. The Laboratory Director confirmed during an onsite interview on 05/05/2020 at 11:30 AM that the laboratory had been performing and reporting the Coronachek test since April 2020 and there were no policies or procedures for competency assessment and no records to document the competency of the testing personnel to ensure accurate reliable test results from April 2020 to May 2020.</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and testing personnel interview, the laboratory failed to establish and follow quality assessment policies and procedures to monitor, assess, and correct problems identified with general laboratory systems of Coronachek COVID-19 IgG/ IgM test testing for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) . Findings include: 1. During an onsite complaint investigation on 05/05 /2020 there was no documented established quality assessment plan to address patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, or proficiency testing performance available for review on the day of the survey. 2. Testing personnel confirmed during an onsite interview on 05/05/2020 at 11:30am that the laboratory did not have established protocols to evaluate general testing quality of Coronachek COVID-19 IgG/ IgM test in the laboratory for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020).</p>
<p><b>D5300</b></p>	<p><b>PREANALYTIC SYSTEMS</b> CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and testing personnel interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems for test requests and quality assessment for the Coronachek COVID-19 IgG/ IgM test for for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) (See D5305 and D5391)</p>
<p><b>D5305</b></p>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1)</p>

The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on the patient test requisition review and staff interview it was determined that the laboratory failed to ensure the test requisition solicited suitable identifiers of the authorized person requesting the test, specimen source, and time of specimen collection for 2 of 2 patients requisitions reviewed for the Coronachek COVID-19 IgG/ IgM test. Findings include: 1. During an onsite complaint investigation on 05/05/2020, random patient test requisition review revealed that the laboratory test requisition did not document the following information for 2 of 2 patients reviewed: a. The name and address of the authorized person requesting the test. b. The address of the laboratory submitting the specimen c. The source of the specimen d. The time of specimen collection. 2. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:00am that the laboratory had been performing and reporting the Coronachek test since April 2020 and failed to ensure the test requisition solicited suitable identifiers of the authorized person requesting the test, specimen source, and time of specimen collection for 2 of 2 patients requisitions reviewed.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on the absence of laboratory policies and procedures and staff interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems for Coronachek COVID-19 IgG/ IgM test for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). Findings include: 1. During an onsite complaint investigation on 05/05/2020, laboratory policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the immunology preanalytic systems were unavailable for review. 2. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:00am that policies and procedures for an ongoing mechanism to monitor, assess and correct preanalytic problems for the Coronachek COVID-19 IgG/IgM test had not been developed, approved, or maintained for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) .

**D5400**

**ANALYTIC SYSTEMS**

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on lack of documentation and testing personnel interview, the laboratory failed to ensure the overall quality of the analytic systems in the laboratory was monitored and evaluated for procedure manual, test temperatures, performance verification and establishment, control procedures, and quality assessment for the Coronachek COVID-19 IgG/IgM test for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) . (See D5403, D5413, D5421, D5449, D5790 and D5791).

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on lack of documentation and confirmation by testing personnel, the laboratory failed to establish and maintain a written policy manual on performing patient preparation, the reportable range, corrective action to take when control results fail to meet the laboratory's criteria for specimen acceptability, imminently life-threatening test results or panic values, and description of the course of action to take if a test system becomes inoperable for the Coronachek COVID-19 IgG/ IgM test for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). Findings include: 1. During an onsite complaint investigation on 05/05/2020, established and approved policies for the following laboratory processes were unavailable for review: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and

rejection b. The reportable range for test results for the test system as established or verified c. Control procedures d. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability e. Imminently life-threatening test results, or panic or alert values f. Description of the course of action to take if a test system becomes inoperable 2. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:30 am that the laboratory had been performing and reporting the Coronachek since April, 14 2020 and failed to establish and maintain a written policy manual on performing patient preparation, the reportable range, corrective action to take when control results fail to meet the laboratory's criteria for specimen acceptability, imminently life-threatening test results or panic values, and description of the course of action to take if a test system becomes inoperable for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) .

**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 review of the Coronachek COVID-19 IgG/IgM package insert review, lack of documentation and staff interview, it was determined that the laboratory failed to monitor and document acceptable room and humidity recordings for two of two months reviewed (April through May 2020). Findings include: 1. Review of the Coronachek COVID-10 IgG/IgM package insert revealed that the test kit must be stored at 2 to 30 degrees Celsius. 2. During an onsite complaint investigation on 05/05. 2020, there was no documented room temperatures available for review for two months reviewed (April through May 2020) 3. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:30am that the laboratory been performing and reporting the Coronachek test since April 14,2020 and had failed to maintain proper room temperature recordings for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) .

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and laboratory director interview, it was determined

that the laboratory failed to complete the performance specifications (accuracy, precision, reportable range) for the Coronachek COVID-19 IgG/IgM test prior to patient testing for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). Findings include: 1. During an onsite complaint investigation on 05/05/2020, documentation of performance specifications evaluations (accuracy, precision, reportable range) for the Coronachek COVID-19 IgG/IgM test was unavailable for review. 2. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:20 am patient testing was being performed since April 14, 2020 and that performance specifications evaluations (accuracy, precision, reportable range) for the Coronachek COVID-19 IgG/IgM had not been performed or documented for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020).

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on Coronachek COVID-19 IgG/IgM package insert, lack of documentation, and testing personnel interview, it was determined that the laboratory failed to document at least two levels of acceptable quality control before patient testing for 2 of 2 months reviewed (April through May 2020). Findings include: 1. Review of Coronachek COVID-19 IgG/IgM package insert revealed that external positive and negative controls are recommended as part of the test process prior to patient testing. 2. During an onsite complaint investigation on 05/05/2020, documentation of daily external controls was unavailable for review. 3. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:15 am that the laboratory had been performing and reporting the Coronachek and test since April 14, 2020 and had failed to perform and document at least two levels of acceptable external quality control before patient testing for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020).

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on package insert review, lack of documentation, and testing personnel interview, the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems associated with policies and procedures, room temperatures, establishment and verification studies, and acceptable quality controls for the Coronachek COVID-19 IgG/IgM test for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020)(see D5403, D5413, D5421, and D5449).

<p><b>D5800</b></p>	<p><b>POSTANALYTIC SYSTEMS</b> CFR(s): 493.1290</p> <p>Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and testing personnel interview, the laboratory failed to ensure the overall quality of the post-analytic systems in the laboratory was monitored and evaluated for test reporting and quality assessment for the Coronachek COVID-19 IgG/IgM test for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). (See D5805 and D5891).</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on random patient record review and testing personnel interview, it was determined that the laboratory failed to ensure that Coronachek COVID-19 IgG/IgM patient test reports included the testing address location and specimen source for 2 of 2 patient reports reviewed. Findings include: 1. During an onsite complaint investigation on 05/05/2020, random patient test requisition review revealed that the laboratory test requisition did not document the following information for 2 of 2 patients reviewed: a. The address of the testing location b. The source of the specimen 2. The laboratory director confirmed during an onsite interview on 05/05/2020 at 11:00am that the laboratory had been reporting Coronachek COVI-19 IgG/IgM test results since April 14, 2020 and failed to ensure the Coronachek COVID-19 IgG/IgM patient test reports included the testing address location and specimen source for 2 of 2 patient reports reviewed.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p>

	<p>This STANDARD is not met as evidenced by:  Based on lack of documentation, and testing personnel interview, the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems associated with an incomplete test report for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020) (see D5805).</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b>  CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by:  Based on review of lack of documentation and staff interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). (see D6078, D6082, D6093, D6103, and D6106)</p>
<p><b>D6078</b></p>	<p><b>LABORATORY DIRECTOR QUALIFICATIONS</b>  CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic</p>

Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on lack of documentation and laboratory director interview, the laboratory failed to ensure that the laboratory director was qualified to manage and direct the laboratory personnel and performance of high complexity Coronachek COVID-19 IgG/IgM testing as outlined in outlined in subpart 493.1441 through 493.1443 for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). Findings include: 1. During an onsite complaint investigation, documentation of the laboratory directors educational qualifications and training were unavailable for review. 2. The laboratory director confirmed during an onsite complaint investigation on 05/05/2020 at 11:30am that he was the laboratory director since April 14, 2020 through May 5, 2020 and did not possess the current educational or training requirements for a high complexity laboratory director as outlined in subpart 493.1441 through 493.1443.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on lack of documentation and testing personnel interview, the laboratory director failed to ensure testing systems used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing of Coronachek COVID-19 IgG/IgM testing for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). (see D5300, D5400 and D5800)

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on lack of documentation and testing personnel interview, the laboratory director failed to ensure that the quality control programs were established and maintained to ensure the quality of Coronachek COVID-19 IgG/IgM testing for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). (see D5449)

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical

phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and staff interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain competency of testing personnel for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020). (see D5209)

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and testing personnel interview, the laboratory director failed to ensure that an established and approved procedure manual was available to testing personnel for 21 of 21 days reviewed (April 14, 2020 through May 5, 2020)(see D5407).