STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVEACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 73  3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 4. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) the laboratory failed to ensure there was an ongoing mechanism to monitor, assess and when indicated, correct problems in the analytic systems.	D5791		
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves	D5800		8Mar2021

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D5800	Continued From page 74 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. This Condition is not met as evidenced by: Based on the severity of the deficiencies cited herein, it was determined that the condition Postanalytic Systems was not met as mandated by CLIA in Subpart K of Title 42 of the Code of Federal Regulation. Findings included: 1. The laboratory failed to ensure the electronic system(s) it used, accurately and reliably transmitted patient-specific data from the point of data entry to final report destination. (See D5801). 2. The laboratory failed to ensure its test results provided the correct interpretation for SARS-CoV-2 (See D5805). 3. The laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results (See D5807). 4. The laboratory failed to ensure it updated their clients regarding changes in the interpretation of results (See D5809). 5. The laboratory failed to ensure it updated clients when the laboratory failed to release patient test results on time (See D5815).	D5800	**Findings 1-7**: please see response to findings at D5801, D5805, D5807, D5809, D5815, D5821, and D5891 below. **Summary**: In regard to the 19 samples in question (D5801), we have verified that the samples were handled in accordance with the standard operating procedure (SOP) in place on December 10, 2020 (CA-SOP-RPT-002). Based on the input from the CDPH laboratory directors', it was determined that results with IC dropout were better characterized as Invalid results. This change in classification was implemented via the onsite CDPH lab directors' discretion on December 11, 2020 with the SOP approved on December 13, 2020. During these two days, results were manual reported and staff were trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a LIMC update was implemented into production to automated result code calculation thereby reducing any manual intervention by the data analyst staff. Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (< 37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 - < 42) were interpreted as inconclusive • 25Jan2021 – present – high Ct values (> 37 - < 42) were interpreted as presumptive positive The laboratory maintains duplicate original reports in addition to issuing amended reports with original results.	

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D5800	Continued From page 75 6. The laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report (See D5821) 7. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891)	D5800		
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This Standard is not met as evidenced by: Based on direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure	D5801	**The below details are for D5801, D5805, D5807, D5809, D5821 1a** In regard to the 19 samples in question (D5801), we have verified that the samples were handled in accordance with the standard operating procedure (SOP) in place on December 10, 2020 (CA-SOP-RPT-002). Based on the input from the CDPH laboratory directors', it was determined that results with IC dropout were better characterized as Invalid results. This change in classification was implemented via the onsite CDPH lab directors' discretion on December 11, 2020 with the SOP approved on December 13, 2020. During these two days, results were manual reported and staff were trained by the CDPH lab directors until the LIMC changes were implemented. On December 13, 2020, a LIMC update was implemented into production to automated result code calculation thereby reducing any manual intervention by the data analyst staff. Please refer to the Analysis Timeline. • 28Oct2020 – 11Nov2020 – results were reported as per the IFU (cutoff < 42 as positive) • 11Nov2020 – 11Dec2020 – a lower Ct cutoff (< 37) was set for positive results based on Ct value observed during validation, reflecting a change in interpretation from the IFU • 11Dec2020 – 25Jan2021 – high Ct values (> 37 - < 42) were interpreted as inconclusive • 25Jan2021 – present – high Ct values (> 37 - < 42) were interpreted as presumptive positive	8Mar2021

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D5801	Continued From page 76 the electronic system(s) it used accurately and reliably transmitted patient-specific data, from the point of data entry to final report destination. Findings included: 1. The laboratory subcontracts the preanalytic and postanalytic phases of testing to an outside entity, COLOR. 2. The following 13 final patient test reports emailed by the laboratory on 01/06/2021 were reported as "Negative" for SARS-CoV-2. a. The laboratory LIMC LIS report sent by the laboratory to the examiners via e-mail on 12/22/2020 showed a result of "Not Detected" for SARS-CoV-2. b. The final test result generated by COLOR showed a final result of "Negative"	D5801	**Continued from page 76** **(1) Immediate Corrective Action:** N/A, The specimens in question were resulted as per SOP. A look forward from December 13, 2020 to December 31, 2020 verified that all samples were reported per SOP versions 2 and 3.1. **(2) Patient Impact:** N/A, based on the lookback from October 28, 2020 to December 11, 2020, there were 8,756 samples with results of IC Dropout that were reported consistent with the SOP that was in effect by written approval from the CDPH lab directors. Results were correctly reported as inconclusive pursuant to the lab SOP. Additionally, per Lab Director Dr. Rosendorff, the future change in definition would not be a change in diagnosis, treatment, or recommended patient action (retesting), and there would not be patient harm. **(3) Preventative Action:** No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. A daily checklist is being completed at shift change by the Data Analyst staff and verified by the Sign Out Manager. **(4) Monitoring Mechanism:** Monthly audits for data integrity are performed as stipulated in the 2021 audit schedule by the Quality organization. The February audit confirmed that the results matched the current SOP and process 100% of the time. **Attachment 1:** Sample Look Back and Look Forward **Attachment 2:** 2021 Audit Schedule **Attachment 3:** End to End Audit Plan **Attachment 4:** 2021Audit-004 Report	

NOT DETECTED	LIMC Report	Final Test Report
[redacted]	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2

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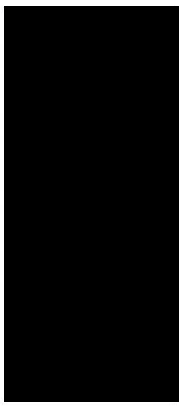
D5801	Continued From page 77 3. Review of the e-mail communication sent by the Director of Clinical Informatics on 12/13/2020, and review of the 32 patient test records obtained by the examiners on December 16, 2020 showed: a. Thirteen (13) patient results were reported as "Not Detected" when it should have been reported "Inconclusive" on December 10, 2020. Reported as Not Detected, but should be reported as Inconclusive  b. Nineteen (19) patient results were reported as "Inconclusive" when it should have been reported as "Invalid" on December 10, 2020.	D5801		

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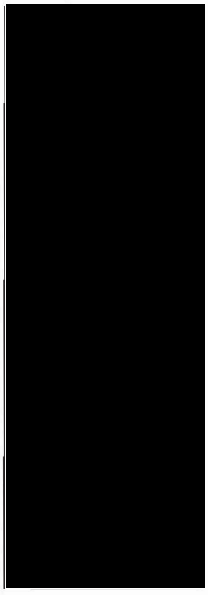
D5801	Continued From page 78 Reported as Inconclusive but should be reported as Invalid.  4. The laboratory failed to show the electronically transmitted results between its LIMC LIS, and the outside entity subcontracted by the laboratory, were periodically verified for accuracy. 5. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 6. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the electronic system(s) used by the laboratory, accurately and reliably transmitted	D5801		

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D5801	Continued From page79 patient-specific data, from the point of data entry to final report destination.	D5801		
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 direct observation, interviews with laboratory staff on December 8, 9, and 16, 2020, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, random review of patient test records covering the period from 12/04/2020 to 12/10/2020, for 32 out of 32 patient test records reviewed, it was determined that the laboratory failed to ensure its test report provided the correct interpretation for SARS-CoV-2. Findings included: 1. Based on interview with the laboratory director on 12/08/2020, there were several patient test results reported in error as a result of incorrect data analysis and interpretation, such as: a. "Not Detected" for SARS-Cov-2 should have	D5805		8Mar2021

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D5805	Continued From page 80	D5805		

been "Inconclusive"
b. "Inconclusive" for SARS-CoV-2 should have been true "Invalid"

2. Based on review of CDPH Branch Lab LIMC LIS reports emailed on 12/22/2020 and SARS-CoV-2 final patient test reports emailed by the laboratory director on 01/06/2021 from COLOR, the laboratory failed to provide the correct interpretation of results to the patients, and how the laboratory conveyed this information to its clients.

a. In an e-mail communication with the laboratory director on 01/12/2021, the examiners asked if corrected reports were issued for the affected patients. The laboratory director indicated that reports were not amended to provide the correct interpretation of results because COLOR did not have the current system to issue corrected reports.

NOT DETECTED	Reported	Correct Interpretation
[redacted]	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive

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D5805	Continued From page 81	D5805		

INCONCLUSIVE	Reported	Correct Interpretation
[redacted]	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid

3. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.

4. The Laboratory Director affirmed (01/12/2021 at approximately 11:58 a.m.) through email communication that the laboratory failed to ensure its test results provided the correct interpretation for SARS-CoV-2.

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.	D5807	See response started in D5801	8Mar2021

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D5807	Continued From page 82 This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results. Findings included: 1. Based on review of patient test reports for SARS-CoV-2, the laboratory indicated under the test result and specific genes cycle threshold (Ct) value, "To learn more about the technical details of the test, please see the test methodology and limitation section." 2. Review of the test reports methodology and limitation section did not indicate how the laboratory determined its results (Positive, Negative, Inconclusive, and Invalid). The report also indicated its reference, "Perkin Elmer New Coronavirus Nucleic Acid Detection Kit, 2019-nCOv-PCR AUS Instructions for Use (IFU)." Review of Perkin Elmer New Coronavirus Nucleic Acid Detection Kit FDA Approved EUA IFU for PE New Coronavirus Nucleic Acid (Effective Date 03/20/2020, Revised 09/16/2020 and 01/12/2021) indicated only the interpretation for the following: a. Detected b. Not Detected c. Invalid	D5807		

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D5807	Continued From page 83 Review of the updated policies and procedures for analysis and reporting of SARS-CoV-2 Assay (last final version on 12/16/2020) indicated the following interpretations a. Detected b. Not Detected c. Inconclusive d. Invalid 3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results.	D5807		

NOT DETECTED (Should be Inconclusive)	INCONCLUSIVE (Should be Invalid)
[redacted]	[redacted]

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D5807	Continued From page 84 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed on (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure its accurate reference intervals determined by the laboratory were available for the authorized person, or individual responsible for using the test results.	D5807		
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients regarding changes in the interpretation of results. Findings included: 1. Based on email communication with the	D5809	**See response started in D5801**	8Mar2021

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D5809	Continued From page 85	D5809		

laboratory director on 01/12/2021, and review of patients reported on 12/10/2020:

a. Results were reported as "Not detected" or "Negative" but should have been reported as "Inconclusive"

b. Results were reported as "Inconclusive "but should have been true "Invalid"

2. The laboratory failed to ensure it updated their clients regarding change in the interpretation of results. The laboratory's outside entity subcontractor, failed to issue corrected reports because the current system it used is not capable of issuing corrected reports.

3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported out 32 out of 32SARS-CoV-2 patient test results which the laboratory failed to ensure it updated their clients regarding changed in the interpretation of results.

a. Below are test results that were reported as "Negative", but the correct result should have been "Inconclusive"

NOT DETECTED	LIMC Report	Final Test Report
[redacted]	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2
	Not Detected	Negative for SARS-CoV-2

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CDPH BRANCH LABORATORY	28454 LIVINGSTON AVE VALENCIA, CA 91355

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5809	Continued From page 86	D5809		

b. Below are test results that were reported as "Inconclusive", but the correct result should have been "Invalid"

INCONCLUSIVE	Reported	Correct Interpretation
[redacted]	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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D5809	Continued From page 87 4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (01/12/2021 at 11:58 a.m.) through email communication that the laboratory failed to ensure it updated its clients regarding changes in the interpretation of results because the laboratory failed to issue corrected reports.	D5809		
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory staff, the laboratory failed to ensure it updated their clients when the laboratory failed to release patient test results on time. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-CLSRV-SOP-002, Title Specimen Collection, Storage, and Shipping, Effective Date 12/07/2020) stated, "The turnaround time (TAT) for the results is within 24-	D5815	**See response started in D5801**	8Mar2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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D5815	Continued From page 88 48 hours." 2. Based on email communication with the laboratory director on 01/08/2021, that the laboratory start counting for TAT when the samples get to the laboratory. 3. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported 5 out of 32 SARS-CoV-2 patient test results with no documentation of delay in reporting patient test results.	D5815		

Accession #	Collected	Received	Reported	Result
[redacted]	12/04/2020	12/05/2020	12/10/2020	Inconclusive
	12/04/2020	12/05/2020	12/10/2020	Inconclusive
	12/04/2020	12/05/2020	12/10/2020	Inconclusive
	12/04/2020	12/05/2020	12/10/2020	Inconclusive
	12/04/2020	12/05/2020	12/10/2020	Inconclusive

	4. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020. 5. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure it documented delay in reporting patient test results.			
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following:	D5821	**Finding 1a, 2-3** See response in D5801	8Mar2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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D5821	Continued From page 89 (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This Standard is not met as evidenced by: Based on direct observation, review of policies and procedures, quality control (QC) and quality assurance (QA) records, and interviews conducted with the laboratory director, the laboratory through COLOR failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results, and maintained duplicates of the original report. Findings included: 1. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, the laboratory through COLOR failed to perform the following: a. Notification and Issuance of Corrected Reports i. Based on email communication with the laboratory director on 01/12/2021, and review of patients reported on 12/10/2020, "Not detected" but should have been "Inconclusive," and "Inconclusive" but should have been true "Invalid. " The laboratory failed to ensure it notified and issued amended reports to the individual using the test results.	D5821		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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D5821	Continued From page 90	D5821		

ii. Random patient sampling covering the period from 12/04/2020 to 12/10/2020, the laboratory tested and reported 13 out of 13 "Not Detected" but should have been "Inconclusive" and 19 out of 19 "Inconclusive" but should have been "Invalid" for SARS-CoV-2 patient test results.

NOT DETECTED	Reported	Correct Interpretation
[redacted]	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive
	Negative	Inconclusive

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATIONNUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2197416	A. BUILDING _____ B. WING _____	02/17/2021

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D5821	Continued From page 91	D5821		

INCONCLUSIVE	Reported	Correct Interpretation
[redacted]	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid
	Inconclusive	Invalid

b. Maintain duplicates of the original report

i. Based on review of patients test records emailed by the laboratory director on 12/24/2020, the laboratory through COLOR issued amended reports on 12/07/2020 for reported SARS-CoV-2 results on 12/04/2020 without providing the original report.

ii. The following 10 out of 10SARS-CoV-2 patient test results were amended:

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D5821	Continued From page 92	D5821	**Finding 1b, 2-3:** 1. In the event that a report must be amended, both the original and the amended reports are retained. 2. Original and amended versions of the reports affected by the error on 04Dec2020 have been retained. See Attachment 5. **(1) Immediate Corrective Action:** N/A, Duplicates of the original reports are maintained. The amended reports contain the original report's result and date as a reference. **(2) Patient Impact:** N/A, based on a look back from October 28, 2020 to December 11, 2020 the process has been in place to maintain the original and amended report. The amended report maintains the original results, original reported date, as well as the updated results. **(3) Preventative Action:** No revision to SOP or process is placed into use until the Lab Director, Dr. Rosendorff, has provided written approval. **(4) Monitoring Mechanism:** As part of the monthly audits schedule we are auditing for the presence of all original and amended reports. This is stipulated in the 2021 audit schedule that is performed by the Quality organization.	

Accession #	Original Report 12/04/2020	Amended 12/07/2020
[redacted]	Detected	*
	Detected	*
	Detected	*
	Not Detected	*
	Detected	*
	Detected	*
	Detected	*
	Detected	*
	Detected	*
	Detected	*

*Unable to return results for this sample.

Please disregard any previous reports as they were issued in error.

Amended Report: The previously reported result (detected/not detected) is not valid due to a lab process error (Accession #s), Covid-19 Test.

Report Test Date: December 4, 2020

Recommendation: This patient should be retested.

2. Based on the laboratory's annual testing declaration signed by the laboratory director on 12/16/2020, the laboratory reported approximately 430,000 SARS-CoV-2 test results from 11/02/2020 to 12/16/2020.

3. The Laboratory Director affirmed (February 12, 2021 at approximately 2:10 pm) that the laboratory failed to ensure it promptly notified and issued corrected reports to the authorized person or individual using the test results and maintained duplicates of the original report.