Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659938	01/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Electra Memorial Hospital	1207 S Bailey, Electra, TX	

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	Noted deficiencies and plans of correction were discussed with laboratory representatives at the entrance and exit conferences. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 45 CFR 493.1240 Pre-Analytic Systems 493.1403 Moderate Complexity Laboratory Director Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 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. This CONDITION is not met as evidenced by: Based on review of Para-Pak C&S package insert, Biofire FilmArray GI Panel CE-IVD Instruction Booklet, laboratory procedure manual, laboratory specimen transport guide, the laboratory failed to meet pre-analytic system requirements as evidenced by: 1. The laboratory failed to follow manufacturer instructions for the collection of stool specimens for Biofire FilmArray GI Panel. Refer to D5311.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of Para-Pak C&S (Culture and Sensitivity) package insert, Biofire FilmArray GI (GastroIntestinal)Panel CE-IVD Instruction Booklet, laboratory procedure manual, laboratory specimen transport guide, and confirm in staff interview, the laboratory failed to ensure collection of stool specimens for Biofire FilmArray GI Panel testing according to manufacturer's instructions. Findings included: 1. Review of BioFire GI Panel package insert (Ref: RFIT-ASY-0104, RFIT-ASY-0116) under Sample Requirements for Stool Specimen Collection stated: "Stool Specimens should be collected in Cary Blair transport media according to manufacturer's instructions." 2. Review of Para- Pak C&S package insert stated in the Specimen Collection and Preparation section that initial collection of stool is acceptable in a thoroughly cleaned bed pan, wide-mouthed container or a plastic bag placed over the toilet seat. Then, stool is added to each container to bring the liquid up to specified fill line. 3. Review of the laboratory procedure for BioFire Filmarray System (signed by the laboratory director on 3/5/2019) in the Specimen section stated that GI panel specimen must be placed in Cary Blair media within 24 hours of collection. 4. Review of the Hospital Laboratory Specimen Transport Guide stated to transport stool in the Stool Collection Container. Stability of the specimen was stated to be stable at room temperature for 24 hours. 5. Review of the Accession & Shipping log from 10/3/2019 through 12/16/2019 revealed 11 GI Panel specimens were received in the laboratory. The following 8 of the 11 specimens did not have a documented received date and time: a. Specimen: 40127656 Collection Date/Time: 10-22-2019/1039 hours Run Date/Time: 10-22-2019/1352 hours b. Specimen: 40137334 Collection Date/Time: 10-17-2019/ 0952 hours Run Date/Time: 10-17-2019 /12:50 hours c. Specimen: 40137304 Collection Date/Time: 10-16-2019/1059 hours Run Date /Time: 10-16-2019/1302 hours d. Specimen: 40136934 Collection Date/Time: 10-08-2019/ 0938 hours Run Date/Time: 10-08-2019/ 1334 hours e. Specimen: 40136713 Collection Date/Time: 10-03-2019/0745 hours Run Date/Time: 10-03-2019/1502 hours f. Specimen: 40137246 Collection Date/Time: 10-14-2019/1333 hours Run Date /Time: 10-14-2019/1828 hours g. Specimen: 40140184 Collection Date/Time:12-16-2019/0932 hours Run Date/Time: 12-16-2019/1304 hours h. Specimen: 40139626 Collection Date/Time:12-05-2019/1355 hours Run Date/Time: 12-05-2019/1927 hours Documentation of date and time of specimens being transferred into Cary Blair media were not provided. 6. In an interview with the laboratory manager at 1116 hours on 1/16/2020, the laboratory manager stated that there was no reference to support the specimen stability at 24 hours. The laboratory manager also stated that stool was received in the lab from local clinics in sterile white collection cups. The laboratory then transfered stool specimens into Cary Blair media. This confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, patient instrument reports, test volume records, and in interview with staff, the laboratory failed to follow their own written policy for repeating complete blood count (CBC) specimens with suspect codes on the Abbott Cell-Dyn Ruby for 2 of 27 patients on 12/12/2019. Findings included: 1. Review of the laboratory's policy stated, "Any SUSPECT code should be repeated. Sample should be placed back on rocker for 15 minutes and repeated." 2. Review of a random sampling of patient instrument reports from 12/12/2019 included the following: Patient #54653 with Suspect Codes "BAND," "NWBC," "RBC MORPH" Patient #54932 with Suspect Code "RBC MORPH" The above patient specimens were not repeated as required in the laboratory's policy. 3. According to test volume records, the laboratory's annual volume was 31,975 hematology tests. 4. During an interview on 01/14/2020 at 12:22 pm, the technical consultant reviewed and confirmed the above findings. 39812 II. Based on review of laboratory procedure manual, patient records, and staff interview the laboratory failed to follow its policy for notification of organisms detected by Biofire FilmArray assay for 5 out of 30 specimens. Findings included: 1. Biofire FilmArray System laboratory procedure manual revised on 10/15/18, reviewed on 02/27/19 and signed by the laboratory director on 3/5/19 under section labeled "Reporting", stated, "If any organism(s) is detected, the nurse or ordering provider will be notified for additional testing". 2. A random review of 30 LIS patient reports revealed the following 5 patient reports: Patient 40127645; Organism detected--Influenza A Patient 40127631; Organism detected--Rhinovirus Patient 40127577; Organism detected--Coronavirus 229E Patient 40127809; Organism detected--Coronavirus 229E Patient 40127767; Organism detected-Metapneumovirus 3. In an interview on 1/16/20 at 1145 hours, the General Supervisor was asked if there was documentation that the above listed detected organisms were communicated to a nurse or an ordering provider. After review of each record, the general supervisor confirmed that there was no evidence of documented communication. The laboratory performs 1175 FilmArray assays per year.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, direct observation, laboratory standard operational procedure manual and confirmed by staff interview, the laboratory failed to follow manufacturer instructions for KOVA Urinalysis System. Findings included: 1. The KOVA Test Procedure stated, "KOVA-Trols I,II and III should be included in each batch to assure proper quality control of physical, chemical

	and microscopic test procedures". 2. A tour of the laboratory on 1/13/20 revealed one bottle of QuanTscopics Urinalysis Microscopics Control Level 2 in the refrigerator in the Hematology/ Urinalysis section of the laboratory. 3. Laboratory operating procedure for Urine Sediment Microscopic Examination under section for Quality Control stated to Perform Level 2 (High) control daily of patient testing. 4. In an interview on 1/14/20 at 1205 hours, the General Supervisor confirmed that QuanTscopics Level 2 was the only urine sediment microscopic control performed by the laboratory. The annual test volume for urinalysis is 2767 tests. II. Based on review of manufacturer's instructions, patient test reports, and confirmed by staff interview the laboratory failed to follow manufacturer instructions for MedTox Profile - V Drugs of Abuse Test System. Findings included: 1. The MedTox Profile-V package insert under "Limitations of the Procedure" stated, "urine samples that are extremely acidic (below pH 4.0) or basic (above pH 9.0) may produce erroneous results". 2. A sample of 16 MedTox Scan test results revealed that pH was not listed for 16 of 16 assays performed. 3. In an interview on 1/15/20 at 1550 hours, the General Supervisor confirmed that pH and adulterants are not tested for Emergency Room patient samples, in-patient samples, and observational patient samples. The laboratory performs 459 toxicology tests annually. III. Based on review of manufacturer's instructions, patient test records, and confirmed by staff interview the laboratory failed to follow manufacturer instructions for Biofire Filmarray Respiratory Panel Assay. Findings included: 1. The FilmArray RP Instruction Booklet stated, "the six assays are not able to reliably differentiate Rhinovirus and Enterovirus ...A positive FilmArray RP Human Rhinovirus/Enterovirus result should be followed - up using an alternate method (e.g., viral culture of sequence analysis)." 2. A random sample of 15 Respiratory Panel patient results were reviewed. 6 of 15 patient results were identified as having Rhinovirus/Enterovirus detected as listed below: 40131751 40131778 40137403 40127631 40137984 40127961 3. On 1/16/20 at 1145 hours, the General Supervisor was asked if any tests were performed to differentiate between Rhinovirus and Enterovirus. After review of the 6 identified results, the general supervisor answered that no follow - up tests were performed. The laboratory performs 1175 Biofire FilmArray assays annually.
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 review of laboratory's verification studies for the Siemens Dimension EXL, the laboratory's linear ranges, and staff interview, it was revealed the laboratory failed to ensure the reportable ranges for 11 of 32 analytes in use were verified by the laboratory's studies. Findings included: 1. Review of the verification studies for the Siemens Dimension EXL chemistry analyzer (Serial Number DE271278) performed on 03/12/2014 revealed the following proven linearity ranges: a. Amylase 0.94 - 750.35 b. Aspartate Aminotransferase 0.0 - 809.64 c. Calcium 2.98 - 14.28 d. Cholesterol 37.15 - 435.53 e. Creatinine 0.810 - 21.510 f. Hemoglobin A1C 4.24 -

	15.72 g. Sodium 83.90 - 162.60 h. Chloride 64.17 - 202.80 i. Lipase 5.0 - 1478.50 j. Triglycerides 0.0 - 914.67 k. Uric Acid 0.12 - 25.16 2. A review of the laboratory's linearity ranges for analytes tested on the Siemens Dimension EXL chemistry analyzer revealed the following ranges in use were not proven by the laboratory's verification studies. a. Amylase Linearity range used: 0 - 650.0 Study results: 0.94 - 750.35 b. Aspartate Aminotransferase Linearity range used: 0.0 - 1000.0 Study results: 0.0 - 809.64 c. Calcium Linearity range used: 5.0 - 15.0 Study results: 2.98 - 14.28 d. Cholesterol Linearity range used: 50.0 - 600.0 Study results: 37.15 - 435.53 e. Creatinine Linearity range used: 0.15 - 20.0 Study results: 0.810 - 21.510 f. Hemoglobin A1C Linearity range used: 3.5 - 16 Study results: 4.24 - 15.72 g. Sodium Linearity range used: 50.0 - 200.0 Study results: 83.90 - 162.60 h. Chloride Linearity range used: 50.0 - 200.0 Study results: 64.17 - 202.80 i. Lipase Linearity range used: 10.0 - 1500.0 Study results: 5.0 - 1478.50 j. Triglycerides Linearity range used: 15.0 - 1000.0 Study results: 0.0 - 914.67 k. Uric Acid Linearity range used: 0.0 - 20.0 Study results: 0.12 - 25.16 3. In an interview with the laboratory manager on 01/13/2020 at 1200 hours in the conference room, after her review of the records, she agreed that the studies performed did not support the linearity ranges in use by the laboratory. This confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the OPTI CCA-TS blood gas analyzer operator's manual, laboratory policy, laboratory maintenance records (01/2019 through 12/2019) and staff interview, the laboratory failed to have documentation of performing weekly maintenance for 12 of 52 weeks in 2019. Findings included: 1. The OPTI CCA-TS operator's manual (PD7040 REV F) stated the following: " 6.2 Weekly Maintenance: Once a week, the Sample Measurement Chamber (SMC) must be cleaned. Open the top cover and clean the optics surface as well as the underside of the SMC cover with a lint-free cloth, dampened with a dilute alcohol or ammonia-based cleaner as needed. Be sure to remove all blood residue. A cotton swab may be used for cleaning smaller parts of the SMC." 2. The laboratory policy titled "OPTI CCA-TS" (signed by the laboratory director 06/18/2019) stated the following: " General Maintenance ... ...B. Weekly Maintenance ....1. Clean the Sample Measurement Chamber (SMC) with gauze, dampened with a dilute alcohol or ammonia-based cleaner as needed. A cotton swab may be used for cleaning smaller parts of the SMC." 3. Review of laboratory maintenance records for the OPTI CCA-TS from 01/2019 through 12/2019 revealed the laboratory failed to perform weekly maintenance for following 12 of 52 weeks in 2019: February 24 - March 2 March 24 - March 30 May 12 - May 18 June 23 - June 29 October 6 - October 12 October 13 - October 19 October 27 - November 2 November 3 - November 9 November 17 - November 23 December 1 - December 7 December 8 - December 14 December 22 - December 28 4. During an interview on 01 /15/2020 at 0920 hours in the respiratory therapy area, the laboratory manager confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory records, quality control (QC) records from 2019, and confirmed in staff interview, the laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the Cardiac Panel and D-Dimer tests performed on the Triage MeterPro analyzer. Findings included: 1. The laboratory policy titled "Triage MeterPro" (signed by the laboratory director on 02/14/2019) stated the following: "A. Frequency of Quality Control and Review .....3. Two levels of external QC are performed with each new lot or reagents (test devices) and every 7 days for Cardiac Panel and D-Dimer test devices." The Cardiac Panel included Troponin, Myoglobin and Creatine Kinase Isoenzyme (CKMB) analytes. 2. Review of laboratory records revealed the laboratory had an Individualized Quality Control Plan (IQCP) for Triage MeterPro, Serial Number (SN) 79041. Two levels of external QC were performed with each new lot or reagents and every 7 days for Cardiac Panel and D-Dimer test devices according to this IQCP. Review of laboratory record from 08/01/2019 revealed the laboratory replaced the Triage MeterPro (SN 79041) analyzer with another Triage MeterPro (SN 85786). The laboratory record titled "Quidel Triage ProMeter Validation, SN#85786" stated, "Two levels of External Quality Control performance; Cardiac and D-Dimer qc was performed 4 times between 08/01 - 08/14 [2019]. No issues. All recovered within 2 S.D." Review of laboratory QC records from 08/01/2019 through 12/31/2019 revealed two levels of external QC were performed with each new lot or reagents and every 7 days for Cardiac Panel and D-Dimer test devices. 3. In an interview on 01/14 /2020 at 1412 hours in the conference, the laboratory manager was asked to provide documentation of an IQCP for the replacement Triage MeterPro to modify the frequency of QC testing for the Cardiac Panel and D-Dimer tests. No documentation was provided. She stated that the laboratory did not have an IQCP for the replaced analyzer and did not run two levels of external QC for 7 days for the Cardiac Panel and did NOT run external QC every 8 hours for 7 days for the D-Dimer Panel in order to modify the frequency of QC testing. This confirmed the findings.
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 Biofire FilmArray Respiratory Panel test reports, laboratory information system (LIS) test reports, FilmArray Respiratory Panel CE-IVD Instruction Booklet, and staff interview, it was revealed the laboratory failed to provide accurate transcription of test results for Influenza A and Human Rhinovirus/ Enterovirus. Findings included: 1. Review of 15 Biofire FilmArray Respiratory Panel patient test results and their corresponding LIS final report revealed the following: a. Patient 40127645 FilmArray analyzer assay report: Equivocal; Influenza A LIS final report: Detected; Influenza A b. 40137984 FilmArray analyzer assay report: Detected; Human Rhinovirus/Enterovirus LIS final report: Detected; Rhinovirus c. 4017961 FilmArray analyzer assay report: Detected; Human Rhinovirus/Enterovirus LIS final report: Detected; Rhinovirus d. 41027631 FilmArray analyzer assay report: Detected; Human Rhinovirus/Enterovirus LIS final report: Detected; Rhinovirus e. 40131751 FilmArray analyzer assay report: Detected; Human Rhinovirus/Enterovirus LIS final report: Detected; Rhinovirus f. 40137403 FilmArray analyzer assay report: Detected; Human Rhinovirus/Enterovirus LIS final report: Detected; Rhinovirus g. 41031778 FilmArray analyzer assay report: Detected; Human Rhinovirus/Enterovirus LIS final report: Detected; Rhinovirus 2. The FilmArray RP Instruction Booklet stated, "the assays are not able to reliably differentiate Rhinovirus and Enterovirus." The laboratory did not follow manufacturer's instructions for using an alternative method to differentiate Rhinovirus and Enterovirus. Refer to D5411, III. 3. In an interview on 1/16/19 at 1145 hours, the General Supervisor confirmed that results were not transcribed into the LIS as shown on the analyzer result report. The laboratory performs 1175 Biofire FilmArray assays per year.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, and laboratory records, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure requirements were met for preanalytic systems. Refer to D6007. 2. The laboratory director failed to ensure verification studies were complete. Refer to 6013. 3. The laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. Refer to 6020. 4. The laboratory director failed to ensure reports of test result included pertinent information required for interpretation. Refer to D6026.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory

	director must-- (E)(1) 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 a review of laboratory policy, laboratory's patient test reports, BioFire Film Array gastrointestinal panel manufacturer's instructions, and staff interview, the laboratory director failed to ensure requirements were met for preanalytic systems, as evidenced by: 1. The laboratory failed to ensure collection of stool specimens for Biofire FilmArray GI Panel testing according to manufacturer's instructions. Refer to D5311.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete, as evidenced by: 1. The laboratory failed to ensure the reportable ranges for 11 of 32 analytes in use were verified by the laboratory's studies. Refer to D5421
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided, as evidenced by: 1. The laboratory failed to follow manufacturer instructions for Quality Control for the KOVA Urinalysis System. Refer to D5411, I 2. The laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the Cardiac Panel and D-Dimer tests performed on the Triage MeterPro analyzer. Refer to D5445.

D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test reports for BioFire Film Array Repiratory Panel, the laboratory director failed to ensure reports of test result included pertinent information required for interpretation. The laboratory failed to provide accurate transcription of test results for Influenza A and Human Rhinovirus/ Enterovirus. Refer to D5805.