Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0534325	04/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Havasu Regional Medical Center	101 Civic Center Ln, Lake Havasu City, AZ	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the number and severity of deficient practices identified during the survey, the Condition: Facility Administration was found to be not met. The laboratory failed to follow established policies to ensure positive identification of blood product recipients, which may have resulted in serious patient harm. (See D3023)
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: Based on review of patient test records, review of laboratory policies and procedures and interview with the facility personnel, the laboratory failed to follow policies to ensure positive identification of a blood or blood product recipient. Findings include:

1. The laboratory performs ABO/Rh testing, manually or automated on the Galileo Echo analyzer, in the specialty of Immunohematology, with an approximate annual test volume of 6,212. 2. The laboratory's established policy titled "Blood Bank General Procedure,", PolicyStat ID: 5087854 states: "Before testing, verify that the information on the order form matches with the label on the sample and the computer. Any discrepancies must be resolved with a redraw if necessary." 3. The general supervisor confirmed that 2 tubes of blood are collected for each patient with blood transfusion test orders. The specimens are labeled with a house label prior to the receipt and accessioning of the sample into the laboratory. The house label includes the following information: patient's first and last name, Medical Record (MR) number, date of birth, patient's physician, date and time of draw, initials of the phlebotomist and initials of the verifier. Blood Bank specimens have order labels that are generated upon entry of the order and the order labels then follow the specimen through all testing processes performed in Blood Bank. There are 4 order labels per specimen which are contained on one perforated sheet, two labels containing a barcode and two labels without a barcode. The order labels contain the following information: patient's first and last name, date of birth, patient's physician, patient number (which is different from MR #), specimen ID#, test ordered, and a barcode on two of the four order labels. The labels that contain the barcode do not contain the patient's date of birth. The barcode label is affixed to the specimen for testing on the Echo analyzer, while the order label that does not contain the barcode is affixed to the Echo instrument printout once testing is complete. 4. During the survey conducted on April 1, 2019 at approximately 11:15, the facility personnel, including the general supervisor, lead testing personnel of Blood Bank, and the hospital's Director of Quality, demonstrated how a specimen was mislabeled during the ABO/Rh type and screen testing process that occurred on 01/01/19 for patient MR# 2003702. The events that occurred on that day were described as follows: An order was placed on 01/01/19 at 05:53 for a 'Type and Screen, Packed Red Blood Cell (PRBC) Unit with Crossmatch' for female patient MR# 2003702. A lab technician pulled a specimen for male patient MR# 2305223 out of the refrigerator and placed it in a rack on the counter which is located directly next to a centrifuge. The female's specimen was already in the centrifuge with the female's order labels placed on the counter in front of the centrifuge. The testing personnel grabbed the male specimen out of the rack and placed the female's order sticker (barcoded label - specimen ID# 4936976) on the male specimen and placed the mislabeled specimen on the Echo analyzer for ABO/Rh type and screen testing. The test was completed at 08:20, resulted as "A positive", the testing personnel entered the test results in the female's electronic medical record (EMR) at 08:25 and the specimen was placed back in the refrigerator. The original instrument printout generated on 01/01/19 for this test was not retained by the testing personnel, however a copy was reprinted from the analyzer and showed the test was performed by user ID ewr6708. Based on the test result entered in the EMR, the female patient was transfused with one unit of "A positive" PRBC. Another order for 'Type and Screen, Packed Red Blood Cell (PRBC) Unit with Crossmatch' was placed for the same patient (MR# 2003702) on 01/01/19 at 10:37. The same testing personnel performed the second test. The facility personnel interviewed during the survey concluded that the testing personnel retrieved the correctly labeled specimen (containing the house label) from the refrigerator and labeled it with the correct order (barcoded) label and placed the specimen on the Echo analyzer for testing. The test result from the second ABO/Rh Type and Screen test for patient MR# 2003702 (specimen ID# 4936976) indicated "O positive". The facility personnel stated that at some point during the second testing process, the testing personnel identified the error and removed the order label from the mislabeled tube used during the first ABO/Rh type and screen test. The instrument printout from the Echo analyzer indicated the test

	result from the ABO/Rh Type and Screen test performed for specimen ID# 4936976, completed at 11:47am by user ID ewr6708, was "O Positive". The test result from the second test was never entered into the patients EMR. Based on the test result from the second Type and Screen test, the female patient was transfused with one unit of "O positive" PRBC. The testing personnel failed to notify anyone of the error. The error was not discovered until 01/03/19 by the blood bank lead during a routine quality review. The correct patient sample was tested on 01/03/19 by the blood bank lead and the test result confirmed the patient's blood type as "O positive". 5. The testing personnel failed to follow established patient/sample identification policies to ensure the positive identification of blood or blood products and the intended recipient, resulting in the error of issuing the incorrect blood type unit, A positive, to patient (MR# 2003072) whose correct blood type is O positive. 6. The facility personnel confirmed that the testing personnel mislabeled a patient's specimen resulting in the transfusion of an incompatible unit of A positive packed red blood cells to a patient with a blood type of O positive.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for services provided in the specialty of Immunohematology, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. See D5311, D5777, D5789, D5800, D5801, D5821, and D5891 for findings.
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 direct inspection of the laboratory's specimen labeling process for Blood Bank specimens that are tested on the Galileo Echo analyzer, review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to establish policies and procedures for labeling samples that are tested on an automated analyzer. Findings include: 1. The laboratory performs ABO /Rh testing, manually or automated on the Galileo Echo analyzer, in the specialty of Immunohematology, with an approximate annual test volume of 6,212. 2. On April 1, 2019 at approximately 11:30, the laboratory personnel stated that a separate barcode label specific to the Echo analyzer must be affixed to the patient specimen which already contains a hospital house label, prior to testing the sample on the analyzer. Lab staff stated that the separate barcode label contains the patient name and sample

	accession number, while the hospital house label on the specimen contains the patient name, medical record number, date of birth (DOB), date and time drawn and the collectors initials. Facility personnel demonstrated the process of affixing the barcode label to the labeled specimen and stated that the top of the barcode label must be placed directly under the patient name on the specimen label and the barcode label was to be folded in such a way that it that only the top portion of the label was attached to the tube. Lab staff stated that during the labeling process, the testing personnel attaching the barcode label is responsible for visually ensuring the patient names match on both labels. 3. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures specific to the labeling process referenced above. 4. The facility personnel confirmed that the laboratory did not have established policies and procedures detailing the labeling process of blood bank specimens that are tested on the Echo analyzer.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of patient test records from the instrument and test results entered into the Laboratory Information System (LIS), and interview with the facility personnel, the laboratory failed to assess patient test results that appeared inconsistent with regard to pertinent clinical data. Findings include: 1. The laboratory's established policy titled, "Blood Bank General Procedure", PolicyStat ID: 5087854, states under the 'Procedure' section: "Check previous record or history of the patient for unexpected antibodies, transfusion reaction, special instructions (i.e. irradiated, leukocyte-reduced, CMV negative) in SafeTrace before starting testing." 2. The laboratory's established policy titled, "SafeTrace TX Applications for BloodBank Technologists", PolicyStat ID: 5087881 states: "Compare and confirm ABO group and Rh Type. Identify, compare and/or confirm the presence of clinically significant unexpected antibodies...Identify, compare and/or confirm difficulties encountered in blood typing; review previous adverse transfusion reactions. All Blood Bank requests and results will be kept for 10 years." 3. Review of patient test records for patient ID# 18765 revealed the patient had two ABO/Rh type and screen tests performed on the Galileo Echo analyzer on 01 /01/19, completed at 08:20 and 11:47, respectively, by user ID ewr6708. 4. The facility personnel stated that the test results from the Echo analyzer do not interface into the Blood Bank LIS, referred to as SafeTrace, therefore testing personnel must manually enter test results from the Echo analyzer to Safetrace. 5. Review of patient test results in Safetrace indicated the testing personnel entered the ABO/Rh type and screen test result into Safetrace as "A Positive" for the test completed at 08:20. No ABO/Rh type and screen test result was entered into Safetrace for the test completed at 11:47 for the patient referenced above, and the corresponding Echo printout indicated the test result as "O Positive". See D3023 and D6175 for findings. 6. No evidence was presented for review during the survey to indicate the testing personnel assessed patient test results at the time of testing to identify inconsistencies in the patient's blood type prior to issuing blood products for transfusion. 7. The facility

	personnel confirmed that the testing personnel failed to identify and assess inconsistent type and screen test results for the patient referenced above prior to issuing blood products for transfusion purposes.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on lack of patient test records, review of laboratory policy and interview with facility personnel, the laboratory failed to retain instrument printouts for patient testing that was performed on the Galileo Echo analyzer. Findings include: 1. The laboratory's established policy titled, "SafeTrace Tx Applications for BloodBank Technologists", PolicyStat ID: 5087881, states: "All Blood Bank requests and results will be kept for 10 years." 2. The facility personnel confirmed that it is the practice of the laboratory to retain the Echo instrument printout after testing, and the order label must be placed on the original copy since the instrument printout does not contain the patients name but the order label does, and labeled printout is required for quality reviews. 3. No evidence was presented for review to indicate the laboratory retained the original instrument printout with the patient's order label affixed to it, for specimen ID# 4936976, performed on the Echo analyzer on 01/01/2019 and entered into the patients EMR at 08:25. See D3023 for findings. 4. The facility personnel confirmed that the laboratory did not have record of the original Echo instrument printout generated on 01/01/2019 for the testing referenced above and indicated that the testing personnel stated the copy was lost when questioned about it.
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 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 number and severity of the deficiencies cited herein, the Condition: Postanalytic Systems was not met. The laboratory failed to ensure that ABO/Rh test results were accurately and reliably sent from the instrument printout to the blood transfusion product ID tag (See D5801). The laboratory failed to report errors for ABO /Rh patient test results to an authorized person ordering the test, and, if applicable, the individual using the test result (See D5821). The laboratory's corrective action procedures failed to identify and correct errors associated with test reporting (See D5891).
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 review of ABO/Rh results indicated on the Echo instrument printouts retrieved from the analyzer, review of the electronic screen print from clinical view observed by nursing staff, review of copies of the transfusion product identification tag documents that are attached to the units to be transfused and interview with laboratory personnel, the laboratory failed to ensure tests results received on January 1, 2019 from the Echo instrument for patient sample ID # 4936976 (patient #8972546) were accurately and reliably sent from the printed results from the echo to the the information on the transfusion product ID tag documents in a timely manner. 1. Patient sample ID #4936976 (pt #8972546) was tested twice for ABO/Rh on the Echo instrument on January 1, 2019. The first test was completed at 8:20 and the second test was completed by 11:47 both by operator #ewr6708 according to the printouts from the Echo. The results retrieved from the analyzer for the first test indicated an ABO/Rh of 'A positive' and the second result indicated an ABO/Rh of 'O positive'. The patient was transfused twice. The patient was transfused with an A positive unit of packed red blood cells (prbc) the first time and an O positive unit of prbc the second time. The original ABO/Rh test report for the first test with the patient label indicated on it was missing at the time of the survey. 2. The electronic screen print of the clinic view observed by the nursing staff indicated an initial ABO/Rh result for pt #8972546 of O positive for the release of an A positive product for transfusion with unit number W041018170483. The second ABO/Rh result for pt#8972546 was missing, but there was still an O positive unit released for transfusion with unit #W041018167551. There was no screen print presented for review that indicated the initial A positive ABO/Rh type result that was indicated on the Echo printout associated with the release of the first unit of A positive prbc. There was no clinic view screen print presented for review that indicated the second O positive ABO/Rh result on the echo printout associated with the release of the second unit of O positive packed red blood cells. The second ABO/Rh test result was never entered by operator #ewr6708 into the Blood Bank LIS referred to as SafeTrace. 3. The transfusion product identification tag for the first red blood cell unit (#W041018170483) indicated a patient ABO/Rh type of A positive and a prbc unit ABO/Rh type of A positive. The transfusion product identification tag for the second red blood cell unit (#W041018167551) still indicated a patient ABO/Rh of A positive and a unit ABO /Rh of O positive even though the second ABO/Rh test on the Echo indicated a patient ABO/Rh of O positive. The second ABO/Rh test result was never entered by operator #ewr6708 into the Blood Bank LIS referred to as SafeTrace. 4. The laboratory personnel could not explain why the second transfusion product identification tag still indicated a patient ABO/Rh type of A positive even though there was a second ABO /Rh test ordered, tested and resulted with an ABO/Rh type of O positive prior to the release of the second unit of O positive packed red blood cells.
D5821	TEST REPORT CFR(s): 493.1291(k)

	When errors in the reported patient test results are detected, the laboratory must do the following: (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 review of patient test results and interview with the facility personnel, the laboratory failed to promptly notify the authorized person ordering the test and, if applicable, the individual using the test result of errors identified during the reporting process of blood type and screen test results. Findings include: 1. Review of patient test results for two separate ABO/Rh type and screen tests performed on 01/01/2019 for patient ID# 18765 revealed erroneous test results, see D3023, D5777 and D6175 for findings. 2. No evidence or documentation was presented for review during the survey to indicate the laboratory promptly notified the authorized person who ordered the tests of reporting errors which were identified by the testing personnel during the testing process. 3. Review of the patients test results in Safetrace, the Blood Bank LIS, indicated the first test result entered at 08:25 was not corrected in the LIS until 01/03 /2019 at 17:15, when the error was identified by the Blood Bank lead technician. The second ABO/Rh type and screen test result was never entered into Safetrace by the testing personnel. 4. No evidence was presented for review during the survey to indicate the laboratory issued a corrected report to the authorized person who ordered the tests once the error was identified. There was no documenation maintained in Safetrace to indicate why the test result was corrected and whether or not a corrected report was issued to the authorized person who ordered the tests. 5. The facility personnel confirmed that the laboratory failed to promptly notify the authorized person who ordered the tests of errors identified with the test results.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of corrective action documents and interview with the facility personnel, the laboratory failed to identify and correct problems associated with test reporting errors. Findings include: 1. The facility personnel interviewed during the survey stated that it is the practice of the laboratory to perform a Root Cause Analysis when errors are identified within the laboratory. 2. The laboratory presented documentation of a Root Cause Analysis (RCA) performed for patient number: 8972546 related to events that occurred on 01/01/2019. The RCA listed the laboratory's response under the section, "Detailed Event Description Including Timeline" as, "92 year old female was admitted to telemetry unit on 12/29/2018 after sustaining a ground level fall while on anticoagulants. On the third day of admission, patient's hemoglobin dropped and patient was typed, cross matched as A positive and received 2 Units of PRBC's. After the first unit of PRBC's was transfused, patient began experiencing gross hematuria. Patient's blood sample was investigated and it

	was found that patient was erroneously typed and cross matched as A positive blood when, in fact, the patient's correct blood type is O positive. Patient was made a DNR with comfort care, per the family's wishes, and transferred on 01/02/19 to hospice." 3. The "Corrective Counseling / Behavioral Accountability Record" presented for review by the hospital's human resource staff for the event indicated above stated, "On 01/01 /19 (testing personnel) made a labeling error in Blood Bank, which resulted in transfusing an ABO incompatible unit that may likely have resulted in serious patient harm." 4. No corrective action documentation was presented for review to indicate the laboratory identified and corrected the problem associated with the testing personnel's failure to report test results and promptly notify the individual responsible for using the test result of test errors. (See D5821 for findings). The laboratory's corrective action documentation provided for review during the survey only referenced the specimen labeling error. 5. The facility personnel acknowledged that the RCA and other corrective action documentation did not identify the testing personnel's failure to report test results in the patient's EMR.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratory Director was not met. The laboratory director failed employ testing personnel who are competent to perform test procedures and record and report test results accurately and proficiently (See D6079). The Laboratory Director failed to ensure that test systems developed and used for Immunohematology testing provide quality laboratory services for all aspects of test performance including preanalytic, analytic and postanalytic phases of testing (See D6082 for findings). The laboratory director failed to ensure that established competency policies and procedures include the assessment of labeling processes and problem solving skills specific to testing in Immunohematology (See D6127).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of patient test records and laboratory policies and procedures specific

	to Immunohematology, the laboratory director failed to employ personnel who are competent to perform test procedures and record and report test results promptly, accurately and proficiently. See D3023, D5777 and D6175.
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 review of the laboratory's test systems for Immunohematology testing and the number and severity of deficiencies cited herein, the laboratory director failed to ensure that test systems developed and used for Immunohematology testing provided quality laboratory services for all aspects of test performance including preanalytic, analytic and postanalytic phases of testing. See D5311, D5777, D5789, and D5800.
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 review of laboratory personnel competency procedures and documents and interview with the facility personnel, the laboratory director failed to ensure that competency policies and procedures included the evaluation of labeling processes and assessment of problem solving skills associated with testing in the specialty of Immunohematology. Findings include: 1. The training and competency form presented for review during the survey, which is used to document initial training of testing personnel and evaluate the competency of individuals who perform patient testing in the specialty of Immunohematology, failed to include information relevant to the specimen labeling process required for specimens tested on the Galileo Echo analyzer. 2. The training and competency form referenced above failed to include the assessment of problem solving skills for testing personnel who perform and result patient tests in Immunohematology. 3. The facility personnel acknowledged that the laboratory's competency evaluation process for personnel who perform patient testing in the specialty of Immunohematology lacked the above procedures required to assess laboratory personnel competency.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation for a semi-annual competency evaluation for two testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing during the first year the individual tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began patient testing in May 2018. 2. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began patient testing in July 2018. 3. The facility personnel confirmed that the laboratory failed to have documentation of a semi-annual competency evaluation for the two testing personnel indicated above.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of patient test requisitions, patient test results and interview with facility personnel, the testing personnel failed to follow the laboratory's established procedures for reporting test results. Findings include: 1. It is the policy of the laboratory to record Immunohematology test results in Safetrace, the Laboratory Information System (LIS) specific to the Blood Bank section of the laboratory. 2. Laboratory policy, "Blood Bank General Procedure, PolicyStat ID: 5087854, Procedure Section 4 (f)" reviewed during the survey states, "All test reactions from Galileo Echo or manual method will be recorded in the SafeTrace system". 3. Review of test requisitions for patient ID# 18765, specimen # 4936976 revealed two separate test orders for 'Type and Screen' were electronically entered by the ordering entity on 01/01/19, at 05:53 and 10:37, respectively. The facility personnel confirmed that both patient tests were performed on the Echo analyzer. 4. Review of patient test results in SafeTrace indicated the testing personnel failed to enter the type and screen test results for the second order placed at 10:37. 5. Review of the Echo instrument printouts and test information maintained in the SafeTrace system for the patient referenced above indicated the first test result was entered into Safetrace on 01/01/19 at 08:25. The original instrument printout was not maintained by the laboratory, however a copy showed the test was completed on the Echo test system on 01/01/19 at 08:20 by user ID ewr6708. The test result entered in Safetrace for this test was "A positive". 6. Review of the Echo instrument printout revealed a test was performed and completed for the patient referenced above on 01/01/19 at 11:47, with a test result of "O positive", however this test result was not entered into the Safetrace system. 7. The facility personnel confirmed that both tests were performed by the same testing personnel and the individual failed to follow established policy and enter the second test result into the Safetrace system.
D6179	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(5)

	Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director. This STANDARD is not met as evidenced by: Based on review of patient test records and interview with the facility personnel, the testing personnel failed to immediately notify the general supervisor, clinical consultant or director when a problem was identified that may adversely affect the reporting of test results. Findings include: 1. Review of instrument printouts and test results maintained in the Safetrace LIS for patient ID# 18765 for testing performed on 01/01/19 revealed an inconsistency in test results from two separate ABO/Rh Type and Screen tests performed by the same testing personnel. See D3023 and D6175 for findings. 2. No evidence was presented for review during the survey to indicate the testing personnel immediately notified the general supervisor, clinical consultant or laboratory director once an error was detected with inconsistent blood type test results generated from the same specimen. 3. The facility personnel confirmed that the testing personnel failed to notify anyone of the error and the error was not detected until 01/03 /19 by the Blood Bank lead technician by way of a routine review of patient test results.