

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0664603	<b>(X3) Date Survey Completed</b> 07/26/2023
<b>Name of Provider or Supplier</b> Regence Health Network Ross	<b>Street Address, City, State</b> 3113 Ross Street, Amarillo, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced onsite investigation was conducted for complaint TX22020331 on July 26, 2023. The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.801 Condition: Enrollment and testing of samples; 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based upon review of the Casper report 155 Individual Laboratory Profiles, proficiency testing records, and interview of facility personnel the laboratory failed to avoid inter-laboratory communications of proficiency testing results prior to the final submission date for grading to the proficiency testing agency. (See D2011 and D2013)</p>
<b>D2011</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample</p>

(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based upon review of Casper Reports 155 Individual Laboratory Profiles, proficiency testing records, Lab quality assurance policy and interviews of facility personnel found the laboratory failed to avoid communication of proficiency testing results with other laboratories prior to the submission deadline of the American Proficiency Institute (API) proficiency testing agency in one of three Chemistry Core testing events in 2022. The findings included: 1. Review of the Casper report 155 Individual Laboratory Profiles generated on June 12, 2023 in preparation of recertification inspections for CLIA certificates: 45D0506643 at 125 W. Park Ave. Hereford, TX 79045 45D0664603 at 3113 Ross St. Amarillo, TX 79103 45D0506774 at 410 Canyon Street Plainview, TX 79072 Found that the facilities obtained the same unacceptable score of 60% for Human Chorionic Gonadotropin (HCG) in the 2022 Chemistry Core 1st testing event. 2. Review of the API Performance Evaluations for the 2022 Chemistry Core 1st testing event (obtained through API) on June 12, 2023 found each of the three laboratories (45D0506643, 45D0664603 and 45D0506774) failed to submit acceptable results for two of five samples as follows: a. Sample HCG-02 - the laboratory reported a result of Positive with an expected result of Negative. b. Sample HCG-05 - the laboratory reported a result of Positive with an expected result of Negative. 3. Review of the 2022 Chemistry Core 1st proficiency testing records for 45D0506774 included: a. The original submission forms defined a deadline submission of Wednesday, 2/2/2022 11:59 PM ET and had the following results documented on the bubble sheet by testing personnel: Sample HCG-01 - positive result filled Sample HCG-02 - positive and negative results both filled with an (X) marked through the negative result. Sample HCG-03 - positive result with a (/) marked through the result. Sample HCG-04 - positive result filled Sample HCG-05 - positive and negative results both filled with an (X) marked through the negative result. b. Review of the attestation statement found the testing personnel documented testing completed on 1-13-22 and the Laboratory Director signing on 01/28/2022. c. Review of the 2022 Chemistry Core 1st Event Submitted Result Forms (obtained from API) found the submission time stamp to be January 28, 2022 12:22 PM, with the following results documented: Sample HCG-01 - Positive Sample HCG-02 - Positive Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Positive 4. Review of the 2022 Chemistry Core 1st event proficiency testing records for 45D0506643 included: a. Original submission forms (reviewed onsite during the recertification inspection conducted June 20, 2023) found a deadline submission of Wednesday, 2/2/2022 11:59 PM ET and had the following results documented on the bubble sheets by testing personnel: Sample HCG-01 - positive result filled Sample HCG-02 - negative result filled Sample HCG-03 - positive result filled Sample HCG-04 - positive result filled Sample HCG-05 - negative result filled b. A copy of the results submission form bubble sheet included in the proficiency testing records found results entered as follows: Sample HCG-01 - positive result filled Sample HCG-02 - positive and negative results both filled with an (X) marked through the negative result. Sample HCG-03 - positive result filled Sample HCG-04 - positive result filled Sample HCG-05 - positive and negative results both filled with an (X) marked through the negative result. c. Review of the attestation statement found the testing

personnel documented testing completed on 1/25/2022 and the Laboratory Director signing on 02/16/2022. d. Review of the Submitted Result Forms for the 2022 Chemistry Core 1st Event Submitted (obtained from API) found the submission time stamp to be January 28, 2022 12:25 PM, with the following results: Sample HCG-01 - Positive Sample HCG-02 - Positive Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Positive 5. Review of the 2022 Chemistry Core 1st proficiency testing records for 45D0664603 included: a. The original submission forms defined a deadline submission of Wednesday, 2/2/2022 11:59 PM ET and had the following results documented on the bubble sheet by testing personnel: Sample HCG-01 - positive result filled Sample HCG-02 - positive result filled Sample HCG-03 - positive result filled Sample HCG-04 - positive result filled Sample HCG-05 - positive result filled b. Review of the attestation statement found the testing personnel documented testing completed on 1-13-22 and the Laboratory Director signing on 01/28/2022. c. Review of the 2022 Chemistry Core 1st Event Submitted Result Forms (obtained from API) found the submission time stamp to be January 28, 2022 12:26 PM, with the following results documented: Sample HCG-01 - Positive Sample HCG-02 - Positive Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Positive 6. Review of a forwarded email sent by testing person one (from 45D0506643) on 07/26/2023 at 2:40 PM included the following: "From: [Testing Person one name], Sent: Tuesday, January 25, 2022 10:07 AM; To: [Lab Coordinator name and email address]; Subject: API's" with a PDF attachment titled "SHereford M22012511190." The attachment "SHereford M22012511190" included "2022 Chemistry Core 1st Event Attestation Statement" with two testing personnel's signatures attesting to testing the Serum HCG PT on 01/25/2022 and original submission forms (bubble sheets) with Serum HCG Proficiency results filled as: Sample HCG-01 - Positive Sample HCG-02 - Negative Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Negative The original result forms bubble sheets did not include markings through results. These forms were filled by the testing personnel and submitted to the lab coordinator (who was the lab coordinator for all three laboratories) for entering and reporting to the PT company. The coordinator then entered 45D0664603 HCG PT results for 45D0506643. 7. Review of the Lab Quality Assurance Policy (approved by the Lab director on 10/27/2021) found on page 4: "3.2 Proficiency testing (PT) a. Verify PT is performed in accordance with CLIA guidelines. b. Ensure PT is performed in the same manner as patient testing. c. Ensure a review of graded results is conducted and documented. Verify unsuccessful or unsatisfactory PT events are investigated and corrective actions taken. Document findings and actions." 8. Interviews of facility personnel disclosed the following: a. During interview of the lab coordinator (who was the lab coordinator for all three laboratories )conducted on June 20, 2023 at 11:25 AM for the recertification inspection of CLIA 45D0506643, he confirmed the laboratory received an unsatisfactory score of 60% for HCG in the API Chemistry Core 1st event. When asked about the copy of the original submission form bubble sheets with the negative results marked through, he said he "did not know what the second result page was or when it was repeated." b. During Interview of the lab coordinator June 22, 2023 at 9:23 AM for CLIA 45D0664603, he confirmed the laboratory received an unsatisfactory score of 60% for HCG in the API Chemistry Core 1st event. At 9:39 AM, he went on to confirm the process of PT result entry for all facilities was that he "entered all PT results for all three clinics. Personnel would test the samples at each location and would send him copies of the results and he would enter them into the API results entry pages for each of the clinics. He went on to say that he entered the proficiency results obtained by 45D0664603 lab in the 45D0506643 proficiency kit for HCG." c. During interview of testing personnel one at CLIA 45D0506774 conducted July 26, 2023 at 10:57 AM, she confirmed the procedure for reporting of PT results was for

testing personnel to complete the result submission forms and sign attestations. She stated that they then sent the results to the lab coordinator by scanning the forms and sending by email, and he would enter the results. The email for the 2022 first event was requested and she explained that the lab coordinator must have been there on the date of testing and took the original result forms with him. 9. The laboratory reported their 2022 1st event Serum HCG Proficiency results under a different CLIA number. The laboratory failed to avoid inter-laboratory communications.

**D2013**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based upon review of Casper Reports 155 Individual Laboratory Profiles, proficiency testing records, Lab quality assurance policy and interviews of facility personnel found the laboratory failed to avoid communication of proficiency testing results with other laboratories prior to the submission deadline of the American Proficiency Institute (API) proficiency testing agency in one of three Chemistry Core testing events in 2022. The findings included: 1. Review of the Casper report 155 Individual Laboratory Profiles generated on June 12, 2023 in preparation of recertification inspections for CLIA certificates: 45D0506643 at 125 W. Park Ave. Hereford, TX 79045 45D0664603 at 3113 Ross St. Amarillo, TX 79103 45D0506774 at 410 Canyon Street Plainview, TX Found that the facilities obtained the same unacceptable score of 60% for Human Chorionic Gonadotropin (HCG) in the 2022 Chemistry Core 1st testing event. 2. Review of the API Performance Evaluations for the 2022 Chemistry Core 1st testing event (obtained through API) on June 12, 2023 found each of the three laboratories (45D0506643, 45D0664603 and 45D0506774) failed to submit acceptable results for two of five samples as follows: a. Sample HCG-02 - the laboratory reported a result of Positive with an expected result of Negative. b. Sample HCG-05 - the laboratory reported a result of Positive with an expected result of Negative. 3. Review of the 2022 Chemistry Core 1st event proficiency testing records for 45D0506774 included: a. The original submission forms defined a deadline submission of Wednesday, 2/2/2022 11:59 PM ET and had the following results documented on the bubble sheet by testing personnel: Sample HCG-01 - positive result filled Sample HCG-02 - positive and negative results both filled with an (X) marked through the negative result. Sample HCG-03 - positive result with a (/) marked through the result. Sample HCG-04 - positive result filled Sample HCG-05 -

positive and negative results both filled with an (X) marked through the negative result. b. Review of the attestation statement found the testing personnel documented testing completed on 1-13-22 and the Laboratory Director signing on 01/28/2022. c. Review of the 2022 Chemistry Core 1st Event Submitted Result Forms (obtained from API) found the submission time stamp to be January 28, 2022 12:22 PM, with the following results: Sample HCG-01 - Positive Sample HCG-02 - Positive Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Positive 4. Review of the 2022 Chemistry Core 1st event proficiency testing records for 45D0506643 included: a. The original submission forms for the 2022 Chemistry Core 1st event (reviewed onsite during the recertification inspection conducted June 20, 2023) found a deadline submission of Wednesday, 2/2/2022 11:59 PM ET and had the following results documented on the bubble sheet by testing personnel: Sample HCG-01 - positive result filled Sample HCG-02 - negative result filled Sample HCG-03 - positive result filled Sample HCG-04 - positive result filled Sample HCG-05 - negative result filled b. A copy of the results submission form bubble sheets included in the proficiency testing records found results entered as follows: Sample HCG-01 - positive result filled Sample HCG-02 - positive and negative results both filled with an (X) marked through the negative result. Sample HCG-03 - positive result filled Sample HCG-04 - positive result filled Sample HCG-05 - positive and negative results both filled with an (X) marked through the negative result. c. Review of the attestation statement found the testing personnel documented testing completed on 1/25/22 and the Laboratory Director signing on 02/16/2022. d. Review of the Submitted Result Forms for the 2022 Chemistry Core 1st Event Submitted (obtained from API) found the submission time stamp to be January 28, 2022 12:25 PM, with the following results: Sample HCG-01 - Positive Sample HCG-02 - Positive Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Positive 5. Review of the 2022 Chemistry Core 1st proficiency testing records for 45D0664603 included: a. The original submission forms defined a deadline submission of Wednesday, 2/2/2022 11:59 PM ET and had the following results documented on the bubble sheet by testing personnel: Sample HCG-01 - positive result filled Sample HCG-02 - positive result filled Sample HCG-03 - positive result filled Sample HCG-04 - positive result filled Sample HCG-05 - positive result filled b. Review of the attestation statement found the testing personnel documented testing completed on 1-13-22 and the Laboratory Director signing on 01/28/2022. c. Review of the 2022 Chemistry Core 1st Event Submitted Result Forms (obtained from API) found the submission time stamp to be January 28, 2022 12:26 PM, with the following results documented: Sample HCG-01 - Positive Sample HCG-02 - Positive Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Positive 6. Review of a forwarded email sent by Testing person one (from 45D0506643) on 07/26/2023 at 2:40 PM included the following: "From: [Testing person one name], Sent: Tuesday, January 25, 2022 10:07 AM; To: [Lab Coordinator's name and email address]; Subject: API's with a PDF attachment titled "SHereford M22012511190." The attachment "SHereford M22012511190" included 2022 Chemistry Core 1st Event Attestation Statement with two testing personnel signatures attesting to testing the Serum HCG PT on 01/25/2022 and original submission forms (bubble sheets) with Serum HCG results filled as: Sample HCG-01 - Positive Sample HCG-02 - Negative Sample HCG-03 - Positive Sample HCG-04 - Positive Sample HCG-05 - Negative The original result forms did not include markings through results. These forms were completed by testing personnel and submitted to the lab coordinator for entering and reporting tot the PT company. The coordinator then entered 45D0664603 HCG PT results for 45D0506643. 7. Review of the Lab Quality Assurance Policy (approved by the Lab director on 10/27/2021) found on 4: "3.2 Proficiency testing (PT) a. Verify PT is performed in accordance with CLIA guidelines. b. Ensure PT is performed in the same manner as

patient testing. c. Ensure a review of graded results is conducted and documented. Verify unsuccessful or unsatisfactory PT events are investigated and corrective actions taken. Document findings and actions." 8. Interviews of facility personnel disclosed the following: a. During interview of the lab coordinator conducted on June 20, 2023 at 11:25 AM for the recertification inspection of CLIA 45D0506643, he confirmed the laboratory received an unsatisfactory score of 60% for HCG in the API Chemistry Core 1st event. Asked about the copy of the original submission form (bubble sheets) with the negative results marked through, he said he "did not know what the second result page was or when it was repeated." b. During Interview of the lab coordinator June 22, 2023 at 9:23 AM for CLIA 45D0664603, he confirmed the laboratory received an unsatisfactory score of 60% for HCG in the API Chemistry Core 1st event. At 9:39 AM, he went on to confirm the process of PT result entry for all facilities was that he "entered all PT results for all three clinics. Personnel would test the samples at each location and would send him copies of the results and he would enter them into the API results entry pages for each of the clinics. He went on to say that he entered the proficiency results obtained by 45D0664603 lab in the 45D0506643 PT kit for HCG." c. During interview of testing personnel one at CLIA 45D0506774 conducted July 26, 2023 at 10:57 AM, she confirmed the procedure for reporting of PT results was for testing personnel to complete the result submission forms and sign attestations. She stated that they then sent the results to the lab coordinator by scanning the forms and sending by email, and he would enter the results. The email for the 2022 first event was requested and she explained that the lab coordinator must have been there on the date of testing and took the original result forms with him.

**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 upon review of the Casper report 155 Individual Laboratory Profiles, proficiency testing records, and interview of facility personnel , the laboratory failed to avoid inter-laboratory communications of proficiency testing results prior to the final submission date for grading to the proficiency testing agency. (see D6016)

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based upon review of the Casper report 155 Individual Laboratory Profiles, proficiency testing records, and interview of facility personnel , the laboratory failed

to avoid inter-laboratory communications of proficiency testing results prior to the final submission date for grading to the proficiency testing agency. (see D2011 and D2013)