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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 27D0663768 | (X3) Date Survey Completed 10/03/2022 |
| Name of Provider or Supplier Vitalant | Street Address, City, State 1444 Grand Ave, Billings, MT | |
| 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 |
|---------------------------|---|
| D2000 | <p>ENROLLMENT AND TESTING OF SAMPLES 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 on an off-site review of College of American Pathologists (CAP) proficiency testing (PT) records, laboratory policy, and e-mail communications with the Senior Director of Regulatory Affairs, the laboratory failed to follow their policy to prevent inter-laboratory communication by emailing their results of Event TRC-C 2022 Platelet-Rich Plasma PT on August 24, 2022, to four other facilities prior to the September 13, 2022, testing event cut-off date, resulting in a proficiency testing referral. (Refer to D2011)</p> |
| D2011 | <p>TESTING OF PROFICIENCY TESTING SAMPLES 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 (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</p> |

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 on an off-site review of laboratory policies, College of American Pathologists (CAP) proficiency testing (PT) records for Transfusion-Related Cell Count Survey, Event TRC-C 2022 and e-mail communications, the laboratory failed to ensure staff from laboratory #1 did not communicate the results of five Platelet-Rich Plasma PT samples performed on the Sysmex XN 1000 to four other laboratories prior to the proficiency testing cutoff date of September 13, 2022, resulting in proficiency testing referral. Findings: 1. Review of CAP (TRC-C) Transfusion-Related Cell Count Survey Result Form revealed, "Results are due no later than midnight, Central time: September 13, 2022." 2. Review of laboratory #1 Sysmex XN 1000 records for PT specimens TRC-19, TRC-20, TRC-21, TRC-22, and TRC-23 were run twice on 8/23/2022, 8/24/2022, and 8/28/2022, revealed the first run of each specimen yielded a zero. 3. Review of email communication from laboratory #1 sent to laboratories #2, #3, #4, and #5 on Wednesday, August 24, 2022, stated at 10:13AM, "We are getting ZEROS on our BB module CAP specimens," and again at 10:20 a.m. "So did you guys get Zeros too?" 4. The laboratory failed to follow its policy, "Laboratory Proficiency Testing Surveys" which states, "Rules - Inter-laboratory (this includes center to sub-center) comparison or communication of survey sample test results is strictly forbidden until after the date when results can no longer be sent to the PT agency." 5. Documents submitted on September 28, 2022, by the Senior Director of Regulatory Affairs, revealed the agency self-reported an inter-laboratory PT referral with a SBAR Document (Communication of Proficiency Test Survey Results CAP Case #01764935), which states laboratory #1 disclosed via e-mail on August 24, 2022, their College of American Pathology (CAP) Proficiency Test (PT) Survey Results (BB module CAP specimens TRC-C 2022) for Platelet Rich Plasma Samples ran on the Sysmex (XN1000BB).

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 an off-site review of laboratory policies, College of American Pathologists (CAP) proficiency testing (PT) records for Transfusion-Related Cell Count Survey, Event TRC-C 2022 and e-mail communications, the laboratory director failed to ensure staff from laboratory #1 did not communicate the results of five Platelet-Rich Plasma PT samples performed on the Sysmex XN 1000 to four other laboratories prior to the proficiency testing cutoff date of September 13, 2022, resulting in proficiency testing referral. (Refer to D6089)

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on an off-site review of laboratory policies, College of American Pathologists (CAP) proficiency testing (PT) records for Transfusion-Related Cell Count Survey, Event TRC-C 2022 and e-mail communications, the laboratory director failed to ensure staff members from laboratory #1 did not communicate the results of five Platelet-Rich Plasma proficiency testing samples (TRC-19, TRC-20, TRC-21, TRC-22, and TRC-23) to four other laboratories prior to the proficiency testing cutoff date of September 13, 2022, resulting in proficiency testing referral. Findings: 1. Review of CAP (TRC-C) Transfusion-Related Cell Count Survey Result Form revealed, "Results are due no later than midnight, Central time: September 13, 2022. 2. Review of laboratory #1 Sysmex XN 1000 records for PT samples TRC-19, TRC-20, TRC-21, TRC-22, and TRC-23 were run twice over several days (8/23/2022, 8/24/2022, and 8/28/2022) revealed the first run of each specimen yielded a zero. 3. Review of email communication from laboratory #1 sent to laboratories #2, #3, #4, and #5 on Wednesday, August 24, 2022, stated at 10:13AM, "We are getting ZEROS on our BB module CAP specimens," and again at 10:20 a.m. "So did you guys get Zeros too?" 4. The laboratory director failed to ensure that staff members from laboratory #1 followed its policy, "Laboratory Proficiency Testing Surveys" which states, "Rules - Inter-laboratory (this includes center to sub-center) comparison or communication of survey sample test results is strictly forbidden until after the date when results can no longer be sent to the PT agency." 5. The Senior Director of Regulatory Affairs self-reported an inter-laboratory PT referral on September 28, 2022, with an SBAR Document (Communication of Proficiency Test Survey Results CAP Case #01764935), which stated laboratory #1 disclosed via e-mail on August 24, 2022, their College of American Pathology (CAP) Proficiency Test (PT) Survey Results (BB module CAP specimens TRC-C 2022) for Platelet Rich Plasma Samples ran on the Sysmex (XN1000BB), which lacked documented review by the laboratory director.