

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0904176	(X3) Date Survey Completed 02/20/2019
Name of Provider or Supplier Southwest Medical Associates-Rancho	Street Address, City, State 888 S Rancho Drive, Las Vegas, NV	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on desk review of federal database CASPER Report 155D, College of American Pathologists (CAP) proficiency testing (PT) evaluations, and review of the laboratory's Checklist for Corrective Action, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory PT event performance for two consecutive testing events for the second and third testing events of 2018 for red blood cell counts (60%, 60%), white blood cell counts (60%, 60%), hematocrit (0%, 60%) and hemoglobin (0%, 60%) resulted in unsuccessful proficiency testing performance. Findings include: The laboratory failed to maintain successful participation with the CAP PT program</p>

shown by the unsuccessful performance for red blood cell count, white blood cell count, hematocrit, and hemoglobin for the second and third testing events of 2018. Refer to D2130.

D2128

HEMATOLOGY
CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on desk review of federal database CASPER Report 155D and CAP PT evaluations, and review of the laboratory's Checklist for Corrective Action, the laboratory failed to identify unsatisfactory PT performances in the second testing event of 2018 in red blood cell count (RBC), white blood cell count (WBC), and cell identification/flow differential and failed to take and document remedial action for the failures. Findings include: 1. CASPER Report 155D and CAP PT evaluations reported a score of 60% for RBC, WBC, and cell identification/flow differential and 0% for hematocrit and hemoglobin for the second testing event of 2018. 2. The laboratory's Checklist for Corrective Action for PT samples tested on 5/22/18 did not identify the unsatisfactory PT performances in RBC, WBC, and cell identification/flow differential and no remedial actions were documented. 3. The corrective action documented for PT samples tested on 5/22/18 for the second testing event of 2018 for unsatisfactory performances in hematocrit and hemoglobin with a score of 0% stated, "Staff will be retrained in both handling/testing of challenge specimens and in the understanding of flags and what flags prohibit reporting of results until they are resolved." There was no documentation when the retraining of staff occurred.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on desk review of federal database CASPER Report 155D and CAP PT evaluations, and review of the laboratory's Checklist for Corrective Action, the laboratory did not successfully participate in a PT program. Findings include: 1. The laboratory failed to maintain successful participation with the CAP PT program shown by the unsuccessful performance for red blood cell count (RBC), white blood cell count (WBC), hematocrit, and hemoglobin in the second and third testing events of 2018. 2. CASPER Report 155D and CAP PT evaluations reported the following scores: 2018/2nd Event 2018/3rd Event RBC: 60% 60% WBC: 60% 60% Hematocrit 0% 60% Hemoglobin 0% 60%

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 desk review of federal database CASPER Report 155D, College of American Pathologists (CAP) proficiency testing (PT) evaluations, and review of the laboratory's Checklist for Corrective Action, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory Director was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1407. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program approved by CMS; as described in subpart 1 of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. Refer to 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 on desk review of federal database CASPER Report 155D, College of American Pathologists (CAP) proficiency testing (PT) evaluations, and review of the laboratory's Checklist for Corrective Action, the laboratory director failed to ensure that proficiency testing samples were tested as required. Findings include: 1. The laboratory failed to achieve satisfactory performance for red blood cell count (RBC), white blood cell count (WBC), hematocrit, and hemoglobin in the second and third testing events of 2018 resulting in unsuccessful PT performance. 2. CASPER Report 155D and CAP PT evaluations reported the following scores: 2018/2nd Event 2018 /3rd Event RBC: 60% 60% WBC: 60% 60% Hematocrit 0% 60% Hemoglobin 0% 60%