Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0529155	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Montecito Post Acute And Rehabilitation	51 S 48th St, Mesa, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on Proficiency Testing (PT) reports for 2018 sent to the state agency and review of documentation presented during the survey conducted on November 20, 2018, the laboratory failed to successfully participate in a PT program for the regulated analyte, pH (Blood Gas) under the sub-specialty of Routine Chemistry. Findings include: 1. The laboratory's PT performance was unsatisfactory for the 2nd event of 2018 for the regulated analyte, pH Blood Gas, with a score of 60%. 2. The laboratory's PT Performance was unsatisfactory for the 3rd event of 2018 for the regulated analyte, pH Blood Gas, with a score of 20%.

D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, pH Blood Gas, for the 2nd and 3rd event of 2018 resulting in unsuccessful PT performance. See D2016 for findings.
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 view of three patient test reports (18397, 18357, 17905) from 09/14/2018, 06 /26/2018 and 03/09/2018 respectively, and interview with the laboratory personnel, the laboratory failed to scan each test report into the relevant patient's medical record as required by the laboratory's policy. Findings include: 1. The three reports listed above could not be located in the electronic medical records of the patients. 2. The laboratory personnel indicated that reports were consistently not being scanned per laboratory policy. 3. There was no corrective action presented for review that addressed the lack of test reports being scanned into electronic medical records
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: The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6016 - ensuring that the proficiency testing samples are tested as required under Subpart H.
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 information furnished to the State Agency by the Proficiency Testing (PT) provider and documentation presented for review during the survey conducted on November 20, 2018, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analyte, pH Blood Gas. See D2016 and D6000 for findings.