

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0688923	(X3) Date Survey Completed 04/18/2019
Name of Provider or Supplier Minarets Medical Group Inc	Street Address, City, State 1340 W Herndon Ave Ste 101, Fresno, CA	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of eleven (11) random patient histopathology slide and report sampling from 11/28/2017 to 04/03/2019 and sixty-seven (67) KOH patient test logs from 05/02/2018 to 04/15/2019, review quality control documents, absence of laboratory policies and procedures and an interview with the laboratory personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. The finding included: a. On 04/18/2019 (survey date) no documentation could be retrieve to show that the laboratory had a written policy for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate (See D5417, D5803). b. The laboratory personnel confirmed on 04/18/2019 15:00 that the laboratory did in have a written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. c. The annual testing declaration 04/01/2019 estimated 5,000 histopathology biopsy and 112 KOH test results reported.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of reagents, review of patient test logs for sixty-seven (67) patient KOH results for the presumptive identification for fungus elements and ecoparasites from 05/02/2018 to 04/15/2019 and an interview with the laboratory personnel on 04/18/2019 (survey date), it was determined that the laboratory used expired Potassium Hydroxide (KOH) reagent to examine skin specimen for the identification of fungal elements and ecoparasites presumptive identification between the period cited. The finding included: a. The KOH reagent in use for the examination of skin specimens for fungal elements and ecoparasites had expired date on 04/2018. b. On 04/18/2019 15:00 the laboratory personnel confirmed that the patient specimens were tested using expired KOH reagent from 05/02/2018 to 04/15/2019. c. Based on the laboratory's submitted testing declaration volume (04/01/2019), the laboratory tests and reports approximately 112 mycology tests annually.

D5803

TEST REPORT

CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on review of random patient biopsy slide test results, lack of histopathology slide biopsy reports in the patient's chart, and interview with the laboratory personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings included: a. On 04/18/2019 (survey date) review of eleven (11) random patient histopathology slide biopsy results from 11/28/2017 to 04/03/2019, seven (7) patient histopathology biopsy results could not be found in the patients' final report s (medical record (MR)). Date Accession # MR 02/07/18 417 & 418 No report found 03/05/18 777 & 778 No report found 04/04/18 1250 & 1251 No report found 06/04/18 2072 No report found 07/11/18 2625 No report found 08/08/18 2930 No report found 12/18/18 4877 & 4878 No report found c. The laboratory personnel confirmed on 04/18/2019, 15:00 that the laboratory failed to ensure that test results are maintained on the patient's chart. d. Based on the laboratory's submitted testing declaration volume (04/01/2019), the laboratory resulted and reported approximately 5,070 histopathology final patient test reports annually.

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 laboratory policies and procedures, random review of ten (11) patients test reports from 11//28/2017 to 04/03/2019, and an interview with the laboratory personnel, it was determined that the laboratory failed to have a written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the post analytic quality assessment systems for 2017 and 2019 to the date of the survey. The Findings include: a. The surveyor requested on 04/18 /2019 (survey date) documentation of ongoing quality assessment (QA) for the post analytic system includes assessing practices/issues related to test report monitoring and evaluating the accuracy and completeness of the laboratory's test reports and the laboratory's turn-around times and procedures for notification of test results. b. The laboratory personnel confirmed 04/18/2019 15:00 that the laboratory did not have a written policy and procedure to assess monitor and correct problem in the post analytical systems. c. No documentation could be retrieved at the time of the survey to indicate that the post analytic review was conducted by a designated person for an ongoing mechanism to monitor, assess and, when indicted, correct problems when identified. (See D 5803)