

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0667110	(X3) Date Survey Completed 11/09/2023
Name of Provider or Supplier Ken C Arakawa Md, Inc	Street Address, City, State 1329 Lusitana St Ste 206, Honolulu, HI	
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 a review of laboratory proficiency testing (PT) records and an interview with the general supervisor on 11/9/2023 at 11:00 AM, it was revealed that the laboratory failed to successfully participate in the American Association of Bioanalysts Medical Laboratory Evaluation's (AAB MLE) 2022 qualitative Rheumatoid Factor (RF) PT program. The findings include: 1. The laboratory failed to achieve satisfactory performance scores for its 2022 AAB MLE RF testing in two out of three consecutive PT events. Refer to D tag D2084.</p>
D2084	GENERAL IMMUNOLOGY

CFR(s): 493.837(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 a review of laboratory PT records and an interview with the general supervisor on 11/9/2023 at 11:00 AM, it was revealed that the laboratory failed to achieve satisfactory performance scores for AAB MLE RF testing in two out of three consecutive PT events in 2022. The laboratory performed annual volume of 189 RF tests. The findings include: 1. The laboratory received a zero score for its nonparticipation in the first RF PT testing event. The general supervisor stated the laboratory notified the PT program that the laboratory was not reporting, "testing discontinued due to manufacturing issues". 2. The laboratory received a "Dc" score for the second RF PT testing event. The general supervisor stated the laboratory was not aware that the PT program discontinued sending RF PT samples to the laboratory for testing. 3. The general supervisor stated the CLIA state agency was not notified within the time frame for submitting PT results of the circumstances associated with its failure to participate in the first and second testing events of 2022..

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of laboratory (PT) records and an interview with the general supervisor on 11/9/2023 at 11:00 AM, it was revealed that the laboratory failed to verify the accuracy of RF testing when it did not participate in the first and second AAB MLE RF PT testing events of 2022. The laboratory performed annual volume of 189 RF tests.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on a review of laboratory PT records and an interview with the general supervisor on 11/9/2023 at 11:00 AM, it was revealed the laboratory failed to follow

written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with its unsuccessful participation in AAB MLE 2022 RF PT events. Refer to D tag D2084.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of laboratory maintenance records and an interview with the general supervisor on 11/9/2023 at 10:30 AM, it was revealed the laboratory failed to perform annual preventive maintenance on its Olympus CHS microscope SN 0K0050 in 2021, 2022 and 2023. The general supervisor stated the laboratory did not schedule this annual activity with their maintenance vendor. The laboratory performed an annual volume of 796 urine sediment examinations and 121 hematology manual differentials.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on a review of PT records and an interview with the general supervisor on 11/9/2023 at 11:00 AM, it was revealed that the laboratory director failed to ensure its AAB MLE RF PT reports were reviewed to evaluate the laboratory's performance and to identify problems for corrective actions. The findings include: 1. The laboratory failed to successfully participate in its 2022 AAB MLE RF PT. Refer to D tag D2016. 2. The laboratory failed to achieve satisfactory performance scores for two out of three consecutive AAB MLE RF PT events in 2022. Refer to D tag D2084. 3. The laboratory failed to verify the accuracy of its RF testing during its unsuccessful 2022 AAB MLE RF PT testing period. Refer to D tag D5215. 4. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with its unsuccessful participation in AAB MLE 2022 RF PT events. Refer to D tag D5291.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of laboratory maintenance records and an interview with the general supervisor on 11/9/2023 at 10:30 AM, it was revealed that the laboratory director failed to ensure its quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: 1. The laboratory failed to establish and perform annual preventive maintenance on its Olympus CHS microscope SN 0K0050 in 2021, 2022 and 2023. Refer to D tag D5433.