

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0898396	(X3) Date Survey Completed 05/07/2021
Name of Provider or Supplier Kenneth R Beer Md Pa	Street Address, City, State 1500 N Dixie Hwy Ste 305/307, West Palm Beach, FL	
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
D0000	An announced recertification survey was conducted 5/10/21 at Kenneth R Beer Md Pa, a clinical laboratory in West Palm Beach, Florida. Kenneth R Beer Md Pa is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency attestation sheets and interview with the Laboratory Director, the Laboratory Director failed to sign the attestation sheets for five out of five events reviewed (API Microbiology 2019 3rd Event, 2020 1st, 2nd, and 3rd Events, and 2021 1st Event). The findings included: Review of the API Microbiology proficiency records for (API Microbiology 2019 3rd Event, 2020 1st, 2nd, and 3rd Events, and 2021 1st Event) revealed the Laboratory Director had not signed the attestation statements. Interview on 5/10/21 at 10:05 a.m., the Laboratory Director stated he did not know he had to sign the attestation statements.</p>
D2039	<p>MYCOLOGY CFR(s): 493.827(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended</p>

during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on American Proficiency Institute (API) record review and interview, the laboratory failed to participate in proficiency testing that resulted in a score of zero (0) percent in Microbiology for 2 (2020 2nd Event and 2020 1st Event) out of 5 (2019 3rd Event 2020 1st, 2nd, and 3rd Events, and 2021 1st Events). The findings included: Review of the API records for the 2020 2nd Event and 2021 1st Event Microbiology showed the laboratory received a score of 0% for Potassium Hydroxide (KOH) testing . Notes on the API "Performance Summary" sheet stated "Failure to Participate". Interview on 5/07/21 at 10:15 a.m., the Laboratory Director stated he did not participate in 2020 2nd Event due to COVID and did not notify API and did not participate in the 2021 1st Event.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Histotechnologist, the laboratory failed to ensure the Laboratory Director performed the twice a year accuracy verification testing for two out two years (2019 - 2021) for Scabies testing in the subspecialty of Parasitology. The findings included: Review of Proficiency Testing records revealed there was no documentation of the peer review for Scabies test for the Laboratory Director for two out of two years (2019 - 2021). Interview on 2/04/20 at 10:00 a.m., the Histotechnologist confirmed the Laboratory Director did not perform the twice a year accuracy verification testing because the Laboratory Director had not had any patients with scabies testing.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on American Proficiency Institute (API) record review and interview with Laboratory Director, there was no documentation to indicate that the Laboratory Director ensured that corrective action was taken when API Microbiology proficiency testing was unsuccessful for 5 out 5 (2019 3rd Event, 2020 1st, 2nd, and 3rd Events, and 1st Event 2021). This is a repeat deficiency. The findings included: Review of API Microbiology proficiency testing records for potassium hydroxide preparations (KOH preps) revealed the following results: 2019 3rd Event- 50% 2020 1st Event - 50% 2020 2nd Event - 0% 2020 3rd Event - 50% 2020 1st Event - 0% Interview on 5

/07/2021 at 10:10 a.m., the Laboratory Director confirmed he did not perform the corrective action, but the problem was he was rushed or did not participate.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Histotechnologist, the facility failed to document corrective action when the room temperature and cryostat temperature were out of range for records reviewed June 2019 to May 2021. The findings included: Record review of the "Room Temperature and Humidity Log" revealed that the acceptable range for room temperature on the log was to be 70 - 78 degrees Fahrenheit and was out of range for 76 out of 108 days and review of the "Cryostat Maintenance Log" revealed the acceptable range for the cryostat was to be 18 - 24 degrees Fahrenheit and was out of range for 41 days out of 90 days. The following dates (from June 2019 to May 2021) had room temperatures out of range with no corrective action documented: 1. 06/03/2020: documented room temperature of "82 degrees F" 2. 06/05/2020: documented room temperature of "82 degrees F" 3. 06/22/2020: documented room temperature of "79 degrees F" 4. 06/29/2020: documented room temperature of "79 degrees F" 5. 07/10/2020: documented room temperature of "79 degrees F" 6. 07/15/2020: documented room temperature of "79 degrees F" 7. 07/17/2020: documented room temperature of "79 degrees F" 8. 08/12/2020: documented room temperature of "79 degrees F" 9. 08/17/2020: documented room temperature of "79 degrees F" 10. 08/19/2020: documented room temperature of "79 degrees F" 11. 08/24/2020: documented room temperature of "79 degrees F" 12. 09/02/2020: documented room temperature of "79 degrees F" 13. 09/16/2020: documented room temperature of "79 degrees F" 14. 09/18/2020: documented room temperature of "79 degrees F" 15. 09/23/2020: documented room temperature of "79 degrees F" 16. 09/25/2020: documented room temperature of "79 degrees F" 17. 09/28/2020: documented room temperature of "79 degrees F" 18. 10/07/2020: documented room temperature of "82 degrees F" 19. 10/09/2020: documented room temperature of "82 degrees F" 20. 10/14/2020: documented room temperature of "79 degrees F" 21. 10/16/2020: documented room temperature of "81 degrees F" 22. 10/21/2020: documented room temperature of "81 degrees F" 23. 10/23/2020: documented room temperature of "81 degrees F" 24. 10/26/2020: documented room temperature of "79 degrees F" 25. 10/29/2020: documented room temperature of "82 degrees F" 26. 11/04/2020: documented room temperature of "79 degrees F" 27. 11/06/2020: documented room temperature of "81 degrees F" 28. 11/09/2020: documented room temperature of "84 degrees F" 29. 11/10/2020: documented room temperature of "81 degrees F" 30. 11/13/2020: documented room temperature of "79 degrees F" 31. 11/18/2020: documented room temperature of "81 degrees F" 32. 11/25/2020: documented room temperature of "79 degrees F" 33. 12/11/2020: documented room temperature of "79 degrees F" 34.

12/16/2020: documented room temperature of "79 degrees F" 35. 12/17/2020: documented room temperature of "81 degrees F" 36. 12/28/2020: documented room temperature of "79 degrees F" 37. 12/30/2020: documented room temperature of "79 degrees F" 38. 01/06/2021: documented room temperature of "79 degrees F" 39. 01/08/2021: documented room temperature of "81degrees F" 40. 01/13/2021: documented room temperature of "79 degrees F" 41. 01/15/2021: documented room temperature of "79 degrees F" 42. 01/18/2021: documented room temperature of "79 degrees F" 43. 01/20/2021: documented room temperature of "81 degrees F" 44. 01/22/2021: documented room temperature of "81 degrees F" 45. 01/25/2021: documented room temperature of "79 degrees F" 46. 01/27/2021; documented room temperature of "79 degrees F" 47. 01/29/2021: documented room temperature of "79 degrees F" 48 02/05/2021: documented room temperature of "81 degrees F" 49. 02/10/2021: documented room temperature of "79 degrees F" 50. 02/12/2021: documented room temperature of "79 degrees F" 51. 02/17/2021: documented room temperature of "79 degrees F" 52. 02/19/2021: documented room temperature of "81 degrees F" 53. 02/22/2021: documented room temperature of "81 degrees F" 54. 02/24/2021: documented room temperature of "79 degrees F" 55. 02/26/2021: documented room temperature of "79 degrees F" 56. 03/01/2021: documented room temperature of "79 degrees F" 57. 03/03/2021: documented room temperature of "81 degrees F" 58. 03/05/2021: documented room temperature of "82 degrees F" 59. 03/08/2021: documented room temperature of "79 degrees F" 60. 03/10/2021: documented room temperature of "81 degrees F" 61. 03/12/2021: documented room temperature of "79 degrees F" 62. 03/17/2021: documented room temperature of "79 degrees F" 63. 03/22/2021: documented room temperature of "79 degrees F" 64. 03/24/2021: documented room temperature of "79 degrees F" 65. 03/26/2021: documented room temperature of "81 degrees F" 66. 03/29/2021: documented room temperature of "79 degrees F" 67. 03/31/2021: documented room temperature of "82 degrees F" 68. 04/07/2021: documented room temperature of "79 degrees F" 69. 04/12/2021: documented room temperature of "79 degrees F" 70. 04/14/2021: documented room temperature of "81 degrees F" 71. 04/16/2021: documented room temperature of "79 degrees F" 72. 04/21/2021: documented room temperature of "81 degrees F" 73. 04/23/2021: documented room temperature of "79 degrees F" 74. 04/28/2021: documented room temperature of "81 degrees F" 75. 05/03/2021: documented room temperature of "82 degrees F" 76. 05/05/2021 documented room temperature of "81 degrees F" The following dates (from June 2019 to May 2021) had cryostat temperatures out of range with no corrective action documented: 1. 03/11/2020: documented cryostat temperature of "-26 degrees F" 2. 04/15/2020: documented cryostat temperature of " -26 degrees F" 3. 04/22/2020: documented cryostat temperature of "-26degrees F" 4 . 06/10/2020: documented cryostat temperature of " - 26 degreesF" 5. 06/24/2020: documented cryostat temperature of " -26 degrees F" 6. 07/01/2020: documented cryostat temperature of " - 26 degrees F" 7 . 07/15/2020: documented cryostat temperature of " - 26 degrees F" 8. 08/11/2020: documented cryostat temperature of "-26 degrees F" 9. 08/25/2020: documented cryostat temperature of " -26 degrees F" 10. 09/09/2020: documented cryostat temperature of " -26 degrees F" 11. 11/04/2020: documented cryostat temperature of " -26 degrees F" 12. 11/11/2020: documented cryostat temperature of " -26 degrees F" 13. 11/25/2020: documented cryostat temperature of " -26 degrees F" 14. 01/06/2021: documented cryostat temperature of " - 26 degrees F" 15. 01/20/2021: documented cryostat temperature of " - 26 degrees F" 16. 02/10/2021: documented cryostat temperature of " -26 degrees F" 17. 02/17/2021: documented cryostat temperature of " -26 degrees F" 18. 03/30/2021: documented cryostat temperature of " -26 degrees F" 19. 04/06/2021: documented cryostat temperature of " -26 degrees F" 20. 04/27/2021: documented cryostat temperature of " -26 degrees F" 21. 05/29/2021: documented cryostat temperature of " -26 degrees F" 22. 06/29/2021: documented cryostat

temperature of " -26 degrees F" 23. 07/20/2021: documented cryostat temperature of " -26 degrees F" 24. 08/10/2021: documented cryostat temperature of " -26 degrees F" 25. 08/17/2021: documented cryostat temperature of " -26 degrees F" 26. 08/31/2021: documented cryostat temperature of " -26 degrees F" 27. 09/28/2021: documented cryostat temperature of " -26 degrees F" 28. 10/05/2021: documented cryostat temperature of " - 26 degrees F" 29. 10/12/2021: documented cryostat temperature of " -26 degrees F" 30. 11/30/2021: documented cryostat temperature of " -26 degrees F" 31. 12/07/2021: documented cryostat temperature of " -26 degrees F" 32. 12/14/2021: documented cryostat temperature of " -26 degrees F" 33. 12/21/2021: documented cryostat temperature of " -26 degrees F" 34. 01/04/2021: documented cryostat temperature of " -26 degrees F" 35. 01/11/2021: documented cryostat temperature of " -26 degrees F" 36. 01/18/2021: documented cryostat temperature of " -26 degrees F" 37. 01/25/2021: documented cryostat temperature of " -26 degrees F" 38. 02/08/2021: documented cryostat temperature of " -26 degrees F" 39. 02/15/2021: documented cryostat temperature of " -26 degrees F" 40. 04/05/2021: documented cryostat temperature of " -26 degrees F" 41. 05/03/2021: documented cryostat temperature of " -26 degrees F" Interview on 5/07/2021 at 11:15 a.m., with the Histotechnologist confirmed that no corrective action was documented for out-of-range room temperatures and cryostat temperatures for 2 out of 2 years (June 2019 to May 2020). The Histotechnologist stated she did not have control over room temperature.