

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1070422	(X3) Date Survey Completed 11/15/2018
Name of Provider or Supplier Milam Bogart Dermatology Llc	Street Address, City, State 7400 S Tamiami Trl, Sarasota, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Moh's Technician, the laboratory failed to ensure Chlorazol Black were removed from use after the expiration date. Findings Included: Observations on 11/15/2018 at approximately 10:00 AM revealed a bottle of Chlorazol Black fungal stain (Lot#6259) with an expiration date of 09/15/18, with no other bottles available to be used for testing. Photographic evidence was obtained. A review of the KOH tests which had been completed since 09/15/2018 revealed that KOH proficiency testing had been completed using the expired Chlorazol Black stain. Interview on 11/15/2018 at 11:45 AM the Moh's Technical confirmed that the Chlorazol Black had expired on 09/15/2018.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Moh's Technician, the laboratory</p>

failed to have an effective quality assurance (QA) protocol in place to capture room temperature not being acceptable for 4 months out of 12 months in 2017 and for all months of 2018 (10 months plus part of November) reviewed. Findings Included: Review of temperature logs revealed the acceptable room temperature range was 68 - 80 degrees Fahrenheit. The documented temperature was not acceptable for the following days: 2017 - 05/26 = 81, 06/29 = 81, 06/30 = 82, 07/10 = 82, 11/14 = 81, 11/15 = 82, 11/16 = 82, 11/17 = 83, 11/20 = 83, 12/01 = 81, 12/04 = 81, 12/05 = 81, 12/21 = 83, 2018 - 01/11 = 81, 01/15 = 82, 01/25 = 81, 01/26 = 81, 01/30 = 81, 02/05 = 82, 02/06 = 82, 03/12 = 81, 03/16 = 81, 03/22 = 81, 04/02 = 82, 04/03 = 81, 04/04 = 82, 04/05 = 82, 04/06 = 81, 04/09 = 81, 04/10 = 81, 04/12 = 82, 04/16 = 82, 04/17 = 83, 04/19 = 82, 04/26 = 81, 05/02 = 81, 05/29 = 81, 06/02 = 82, 06/11 = 82, 06/12 = 82, 06/12 = 82, 06/25 = 82, 06/26 = 83, 06/27 = 81, 06/28 = 82, 07/02 = 82, 07/03 = 82, 07/05 = 81, 07/06 = 81, 07/10 = 81, 07/12 = 82, 07/13 = 82, 07/17 = 81, 07/18 = 81, 07/24 = 81, 07/30 = 82, 07/31 = 82, 08/02 = 82, 08/03 = 83, 08/30 = 81, 09/04 = 81, 09/17 = 81, 09/18 = 81, 09/19 = 91, 09/25 = 81, 09/28 = 81, 10/02 = 81, 10/04 = 81, 10/05 = 81, 10/09 = 82, 10/11 = 81, 10/12 = 81, 10/15 = 82, 10/16 = 82, 10/17 = 82, 10/18 = 82, 10/22 = 81, 10/29 = 81, 10/30 = 82, 11/01 = 82, 11/02 = 81, 11/05 = 82, 11/06 = 81, 11/07 = 81, 11/08 = 81, 11/13 = 81, and 11/15 = 81. Review of quality assurance records revealed that quarterly (01/05/18, 04/17/18, and 08/16/2018) a quality assurance checklist was completed. Part of the quality assurance checklist included performance of Quality Control Policies as specified such as obtaining and recording required temperatures. The quality assurance checklist did not include corrective actions for out of range temperatures. Interview on 11/15/2018 at 11:30 AM with the Moh's Technician confirmed the out of range temperatures.