Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2092169	12/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Honet Dermatology	36800 Woodward Avenue Ste 110, Bloomfield Hills, MI	

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
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, lack of documentation, and interview with the Laboratory Liaison (LL), the laboratory failed to verify the accuracy of its mycology and parasitology testing at least twice annually for 3 (fall of 2019, 2020, and spring 2021) of 6 events reviewed for 2 years. Findings include: 1. A review of the Michigan Dermatological Society records revealed a lack of documentation of the mycology and parasitology verification of accuracy testing for 3 of 6 events in 2 years as follows: a. lack of documentation for fall in 2019 and 2020 b. lack of documentation for spring in 2021 2. An interview on 12/01/2021 at 12:23 pm, the LL confirmed the laboratory did not have documentation of the mycology and parasitology verification of accuracy testing as listed above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow the

	"Dermatophyte Test Medium (DTM)" procedure for interpretation of results and the expiration date on the media for 1 (#9) of 3 patient charts audited. Findings include: 1. A review of the 'Hardy Diagnostics DTM Instructions for Use' revealed under "Interpretation of Results" "media should be examined daily for up to fourteen (14) days." 2. A record review for 1 (#9) of 3 patient charts audited revealed the final day of recording the test results exceeded the 14 days as follows: a. date of service 8/24 /2020 - read on 1/05/2021 (134 days) b. media expiration date - lot L27-464020 expired on 12/22/2020 2. During the interview on 12/01/2021 at 1:51 pm, the LL confirmed the final interpretation of the mycology testing exceeded the 14 days and that the DTM media had expired.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to check each lot number and shipment of Dermatophyte Test Media (DTM) for negative reactivity for 2 (December 2019 to December 2021) of 2 years reviewed. Findings include: 1. A record review of the "Quality Control For Fungal Culture Media" procedure for DTM revealed the laboratory was performing control testing with Trichophyton rubrum (Dermatophyte), Candida albicans (Yeast), and a sterility control. 2. A record review for 2 (December 2019 to December 2021) of 2 years revealed a lack of documentation for a true negative (inhibition of growth) for the following lots received a. lot 27-455462 tested on 2/27/2020 b. lot 27-464020 tested on 8/03/2020 c. lot 27-480311 tested on 1/02/2021 d. lot 27-485694 tested on 7 /06/2021 3. An interview on 12/01/2021 at 1:15 pm, the LL confirmed a negative or inhibition of growth control was not used. ***Repeat Deficiency from October 29, 2019***
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on document review and interview with the Laboratory Liaison (LL), the

	laboratory failed to establish a system to ensure the manually transcribed mycology wet mount test results were accurately reported in the "Tissue examination by KOH and A&P" section, and the "Procedure Description" section for 3 (#2, #6, and #7) of 8 patient charts audited. Findings include: 1. Record review revealed for 3 (#2, #6, and #7) of 8 patient charts audited, the "Tissue examination by KOH and A&P" results did not match the "Procedure Description" as follows: a. specimen #2 i. Tissue examination by KOH and A&P section: reported out as KOH Results: Positive Negative ii. Procedure Description: reported out as KOH results: Positive Negative iii. No definitive answer reported b. specimen #6 i. Tissue examination by KOH and A&P section: reported out as KOH results: Negative ii. Procedure Description: reported out KOH results: Positive c. specimen #7 i. Tissue examination by KOH and A&P results: Tissue examination section reported out as "Candida yeast elements were present," A&P section KOH results: Positive Negative ii. Procedure Description: reported out as 'Candida yeast elements were present,' KOH results: Positive Negative iii. No definitive answer reported 2. When queried on 2/01/2021 at 1:39 pm, the LL informed the surveyor that when entering results into the system the KOH results: Positive Negative is pre-populated and the person entering results is to delete the information that is not correct. 3. During the interview on 12/01/2021 at 1:39 pm, the LL confirmed the process of reporting and result entry is not consistent from each section of the reporting result template. ***Repeat Deficiency from 10/29/2021 survey ***