

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2092169	(X3) Date Survey Completed 10/29/2019
Name of Provider or Supplier Honet Dermatology	Street Address, City, State 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to have a request for patient testing for 1 (patient #6) of 12 patient charts audited. Findings include: 1. A review of patient testing logs revealed patient #6 received scabies testing on 4/2/19 with a positive result. 2. A review of the chart for patient #6 revealed a lack of a test request for scabies testing. 3. An interview on 10/29/19 at 9:35 am with the office manager confirmed a test request was not available for patient #6.</p>
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed</p>

to check each lot number and shipment of Dermatophyte Test Media (DTM) for negative reactivity for 2 (October 2017 to October 2019) of 2 years reviewed. Findings include: 1. A record review of the quality control procedure for DTM revealed the laboratory was performing control testing with T. rubrum (Dermatophyte), C. albicans (Yeast), and a sterility control. 2. An interview on 10/29/18 at 9:58 am with the office manager revealed the laboratory uses previous cultures showing no growth to inoculate new lots or shipments of DTM and does not use a live organism to show inhibition of growth by the DTM.

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 record review and interview with the office manager, the laboratory failed to ensure test results were reliably transferred to patient charts for 4 (patients #4, 6, 8, and 9) of 12 patient charts audited. Findings include: 1. A record review of patient testing logs revealed the following patients had testing performed on the following dates: a. Patient #4 on 7/12/18 b. Patient #6 on 4/2/19 c. Patient #8 on 1/11/18 d. Patient #9 on 5/17/18 2. A patient chart audit of the patients tested above revealed a lack of documentation of test reports in the patient charts. 3. An interview on 10/29/19 at 9:50 am with the office manager confirmed test reports for the patients listed above were not available.