

False Positive Results on HSV 2 Confirmatory Test Used at Major US Laboratory Compared to Gold Standard Herpes Western Blot

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BACKGROUND

LabCorp, a major US clinical laboratory, has added a supplemental test, the Biokit HSV-2 Rapid Test, as confirmation for specimens with positive HSV-2 IgG index values between 1.1 and 5.0.

METHODS

Medical records of patients seeking herpes western blots at the Westover Research Group (Portland, Oregon) from Sept. 2021 to Mar. 2022 were reviewed.

RESULTS

Of the 33 subjects, 31 of the subjects who tested positive by Biokit tested negative by western blot and two tested indeterminate.

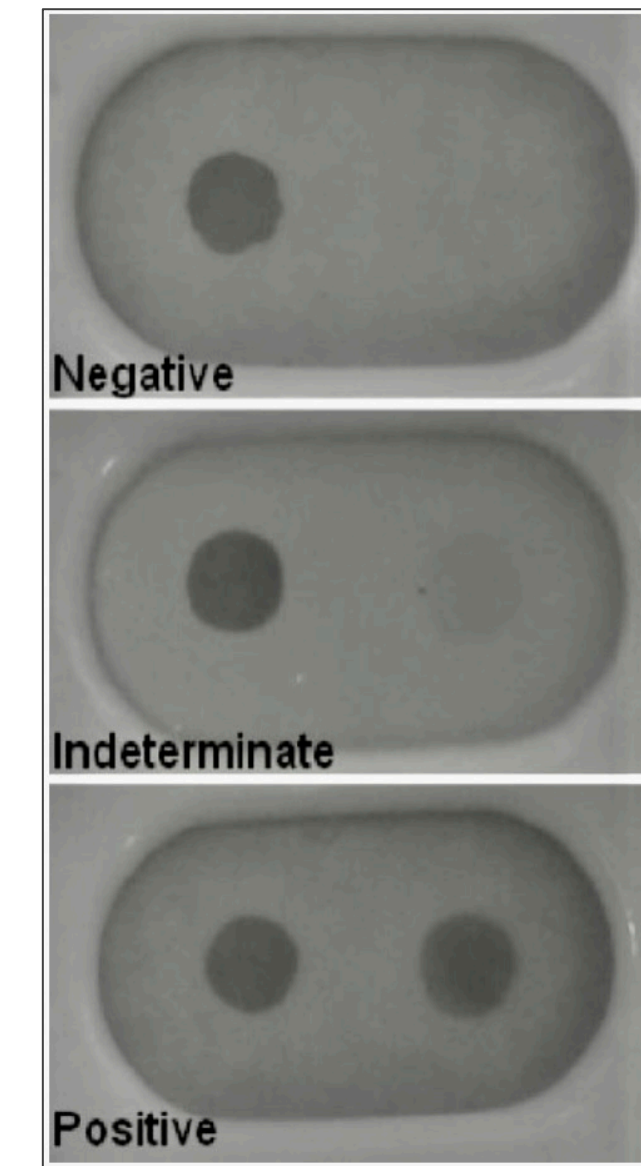
PDF

Further descriptions of our study are in an attached PDF

Would you want to be told you had genital herpes when you really don't?

CONCLUSIONS

Biokit-HSV-2 reflex testing in this laboratory setting had low positive predictive value for Western blot-confirmed HSV-2 infection. Further research to develop accurate HSV-2 immunoassays is urgently needed. Providers should be cautious when providing a diagnosis of HSV-2 infection based on serologic HSV-2 IgG testing without Western blot confirmation. This is a highly stigmatized, psychologically life changing news for people, and we want to be sure it is accurate. Dr. Rhoda Morrow discusses the difficulties with what she called “indeterminate Biokit results” in a 2008 paper. See photo above. Laboratories using this test should consider adding this as a possible result rather than calling any pink color “positive”.



From Dr. Rhoda Ashley Morrow, 2008.



Biokit positive, negative

Subjects	Age	Gender	HSV 2 IgG index	HSV 1
Subject 1	41	F	1	N
Subject 2	29	F	1.2	N
Subject 3	43	F	1.4	N
Subject 4	34	F	1.5	N
Subject 5	39	F	1.5	N
Subject 6	21	F	1.7	N
Subject 7	19	F	2	N
Subject 8	26	F	0.9	P
Subject 9	32	F	1.2	P
Subject 10	29	F	1.3	P
Subject 11	25	F	1.4	P
Subject 12	30	F	1.4	P
Subject 13	26	F	1.6	P
Subject 14	22	F	2.2	P
Subject 15	38	M	1.1	N
Subject 16	41	M	1.2	N
Subject 17	39	M	1.3	N
Subject 18	41	M	1.4	N
Subject 19	34	M	1.6	N
Subject 20	32	M	1.7	N
Subject 21	33	M	2.2	N
Subject 22	34	M	2.6	N
Subject 23	41	M	2.6	N
Subject 24	40	M	3	N
Subject 26	29	M	1	P
Subject 27	27	M	1.2	P
Subject 28	25	M	1.3	P
Subject 29	21	M	1.4	P
Subject 30	22	M	1.6	P
Subject 31	29	M	2.1	P
Subject 32	28	M	3.4	P
Subject 33	40	M	3.6	P
Subject 25	30	M	6.1	N

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