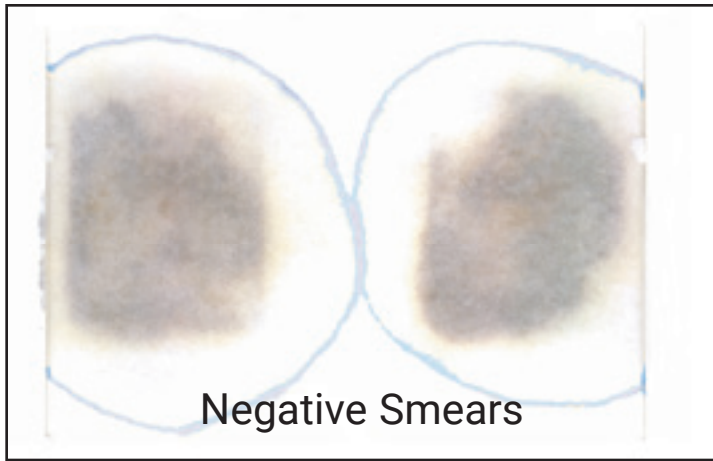


Helena FOBT - Interpreting Results

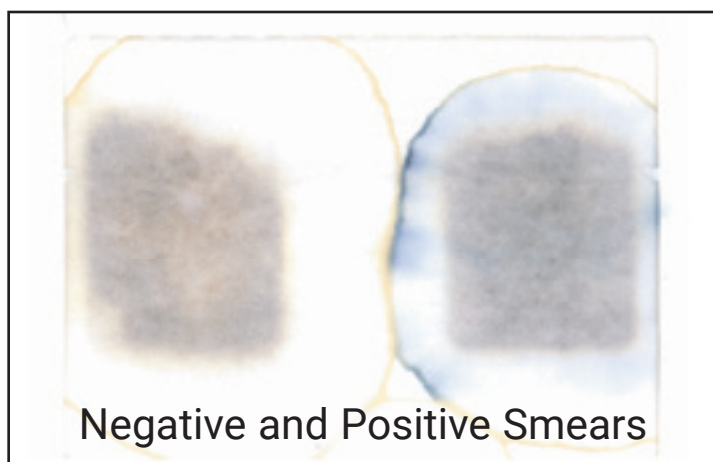
Interpretation of the test should not be done by one who is color blind.



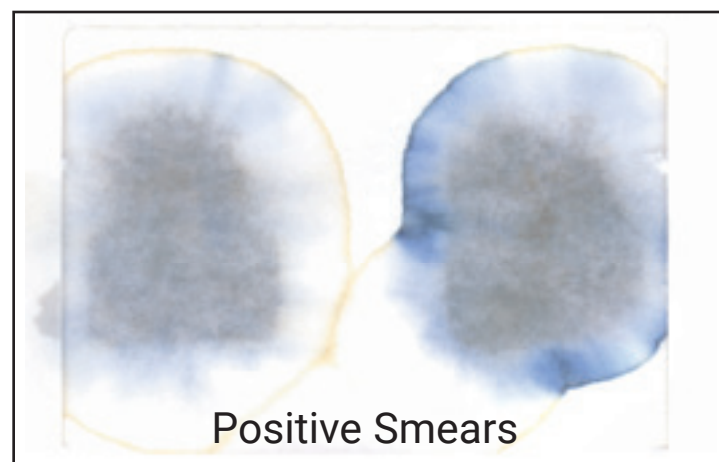
Negative Smears

Sample report: negative

No detectable blue on or at the edge of the smears indicates the test is negative for occult blood. If ColoCheck monitors react properly.



Negative and Positive Smears

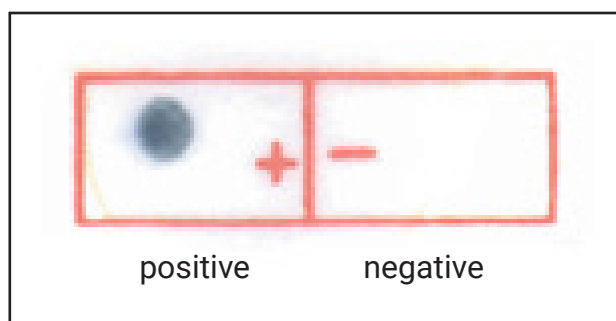


Positive Smears

Sample report: positive

Any trace of blue color within the specimen application area is a positive for occult blood, if ColoCheck Monitors react properly.

On-slide ColoCheck Monitors



positive

negative

If the test system is functional:

- a blue color will appear in the positive ColoCheck Monitors area within 2 minutes.
- no blue color will appear in the negative ColoCheck Monitors area.
- Neither the intensity nor the shade of the blue from the positive ColoCheck Monitor area should be used as a reference for interpreting positive test results.

Interpretation Guidelines

1. "Blueing" as shown in the example at the top of this page can result in improper test interpretation and erroneous results. The blueing effect may be observed when slides are exposed to high temperatures/humidity on storage prior to use. The addition of color developer to these effected slides results in the chromatographic movement of a ring of color to the periphery of the slide window. This ring of blue color fades slowly and is still visible after several hours, and is of course, not to be interpreted as a positive result.

Blueing does not render the slide invalid, any blue color developed within or on the outer edge of the fecal specimen is to be reported a a positive result.

2. Dark colored stools (from foods rich in chlorophyll or containing bismuth, iron, or similar medications) can cause confusion. The greenish discoloration resulting after the application of color developer is not to be confused with the blue color seen when colorless guaiac is oxidized, (in the presence of haemoglobin and hydrogen peroxide) to the blue colored quinone.
3. Ensure the results are read after 30 seconds but within 2 minutes after the addition of Color Developer. Any trace of blue color within or on the outer edge of the specimen is positive. Often the blue color fades rapidly