
CERTEST FOB 50+200

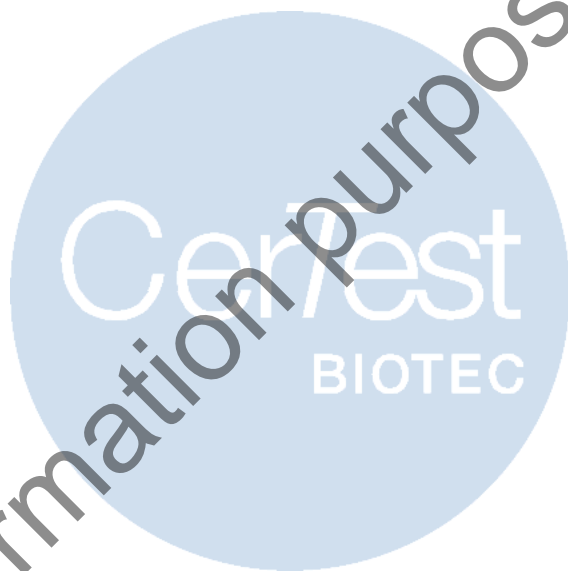
ONE STEP human haemoglobin
COMBO CARD TEST

CERTEST BIOTEC S.L.

For information purposes only



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ENGLISH**INTENDED USE**

CerTest FOB 50+200 one step combo card test is a coloured chromatographic immunoassay (cut-off qualitative test) for the qualitative determination of human haemoglobin (hHb) in stool samples to the following cut-off values: A: 50ng/mL and B: 200ng/mL.

CerTest FOB 50+200 combo card test offers a simple, a highly sensitive and non-invasive screening assay to detect gastrointestinal bleeding (faecal occult blood).

INTRODUCTION

Colorectal cancer is the second leading cause of illness and death in the Western world. The screening using faecal occult blood tests is based on the bleeding detection, as important symptom of colonic neoplasm, either at an early-stage cancer or large adenomatous polyps. Colorectal cancer is also associated with local acute inflammatory reaction being visualized, in some cases, by white cell neutrophil scanning.

Haemoglobin (hHb) is the iron-containing oxygen-transport protein in the red blood cells of all vertebrates that may be leaked into gastrointestinal tract and then discharged with the faeces in gastrointestinal bleeding diseases.

TEST PRINCIPLE

CerTest FOB 50+200 is based on the principle of a cut-off qualitative immunochromatographic assay for the determination of human haemoglobin in stool samples.

Strip A consists of a nitrocellulose membrane pre-coated with mouse monoclonal antibodies on the test line (T), in the results window, against human haemoglobin and with rabbit polyclonal antibodies, on the control line (C), against a specific protein. The label/sample absorbent pad is sprayed with test label solution (mouse monoclonal antibodies anti-human haemoglobin) conjugated to red polystyrene latex and control label solution (specific binding protein) conjugated to green polystyrene latex, forming coloured conjugate complexes.

Strip B consists of a nitrocellulose membrane pre-coated with mouse monoclonal antibodies on the test line (T), in the results window, against human haemoglobin and with rabbit polyclonal antibodies, on the control line (C), against a specific protein. The label/sample absorbent pad is sprayed with test label solution (mouse monoclonal antibodies anti-human haemoglobin) conjugated to red polystyrene latex and control label solution (specific binding protein) conjugated to green polystyrene latex, forming coloured conjugate complexes.

If the sample is human haemoglobin positive, the antigens of the diluted sample react with the red-coloured conjugate complex (anti-human haemoglobin monoclonal antibodies-red polystyrene microspheres) in the strip A, and if the sample is human haemoglobin positive, the antigens of the diluted sample react with the red-coloured conjugate complex (anti-human haemoglobin monoclonal antibodies-red polystyrene microspheres) in strip B, which were previously pre-dried on the absorbent pad. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the binding conjugate complexes migrate. The anti-human haemoglobin antibodies present on the membrane of strip A (test line) and the anti-human haemoglobin antibodies present on the membrane of strip B (test line) capture the coloured conjugate and the red line will be visible in both strips. These bands are used to interpret the result.

If the sample is negative, there is no human haemoglobin presence and yet, the antigens may be present in a concentration lower than the cut-off value, for which the reaction will not take place with any red-coloured conjugate complex. The anti-human haemoglobin antibodies present on the membrane (test lines) will not capture the antigen-red-coloured conjugate complex (not formed), for which the red lines will not appear.

Whether the sample is positive or not, in both strips, the mixture continues to move across the membranes to the immobilized specific antibodies placed in the control lines. The anti-specific protein antibodies present on both membranes will capture control green-conjugate complex and both control lines will always appear. The presence of these green lines serve as: 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) an internal control for the reagents.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date marked on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

PRECAUTIONS

- For professional *in vitro* diagnostic use.
- Do not use after expiration date.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. A new must be used for each sample to avoid contamination errors.
- The tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with skin or mucous membrane. Consult safety data sheet, available on request.
- Components provide in the kit are approved for use in the CerTest FOB 50+200 test. Do not use any other commercial kit component.
- The presence of yellow lines in the results window (control line zone and test line zone), before using the test, is completely normal and does not imply failure of the test functionality.

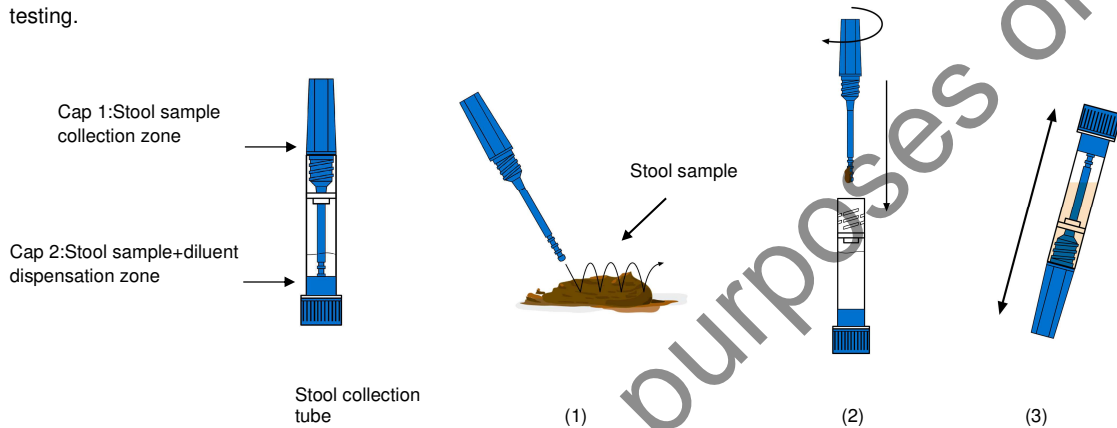
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

SPECIMEN COLLECTION AND PREPARATION

Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20°C. In that case, the sample will be totally thawed and brought to room temperature before testing. Homogenise stool sample as thoroughly as possible prior to preparation.

Specimen preparation (see illustration):

1. Take out the cap 1 of the stool collection tube and use the stick to pick up sufficient sample quantity. Introduce the stick once into 4 different parts of the stool sample (1), making sure that, in each insertion, the stick's screw is covered with the sample to take the appropriate amount of stool. Then, introduce the sample in the stool collection tube (2). For liquid samples, add approx. 20µL in the stool collection tube using a micropipette.
2. Close the tube with the diluent and stool sample (2). Shake the tube in order to assure good sample dispersion (3). The stool collection tube with dilute sample can be stored until 2 days at room temperature or until 5 days in the refrigerator (2-8°C) prior to testing.



Precautions: Patients suffering from menstrual period, bleeding hemorrhoids, blood in urine or strain during bowel movement should not collect samples.

MATERIALS

MATERIALS PROVIDED

- CerTest FOB 50+200 combo card tests
- Instructions for use
- Stool collection tubes with diluent

MATERIALS REQUIRED BUT NO PROVIDED

- Specimen collection container
- Disposable gloves
- Timer

TEST PROCEDURE

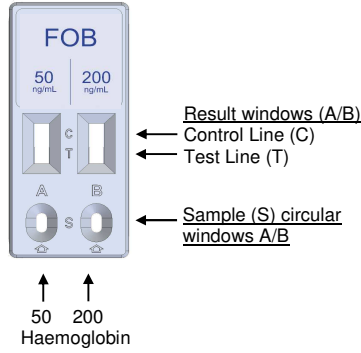
Allow tests, stool samples and controls to reach room temperature (15-30°C) prior to testing. Do not open pouches until the performance of the assay.

1. Proceed to shake the stool collection tube in order to assure good sample dispersion.
2. Remove the CerTest FOB 50+200 combo card test from its sealed bag just before using it.
3. Take the stool collection tube, open the cap 2 (4) and dispense 3 drops in the circular window marked with the letter A (5) and 3 drops, using the same tube, in the circular window marked with the letter B (6). Avoid adding solid particles with the liquid.
4. **Read the result at 10 minutes.** Do not read the test result after more than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window (S) with the stick. If it doesn't work, dispense a drop of diluent until seeing the liquid running through the reaction zone.

CERTEST FOB 50+200

One Step test to detect haemoglobin (50 ng/mL and 200 ng/mL) in combo card format /
 Prueba combo de un solo paso para detección de hemoglobina (50 ng/mL y 200 ng/mL) en formato cassette.

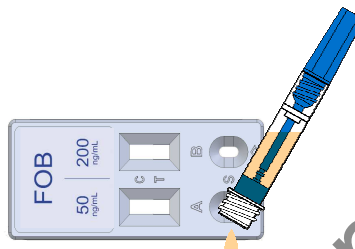
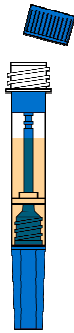


FOB 50 Strip A-Procedure

Add 3 drops in A-circular window.

FOB 200 Strip B-Procedure

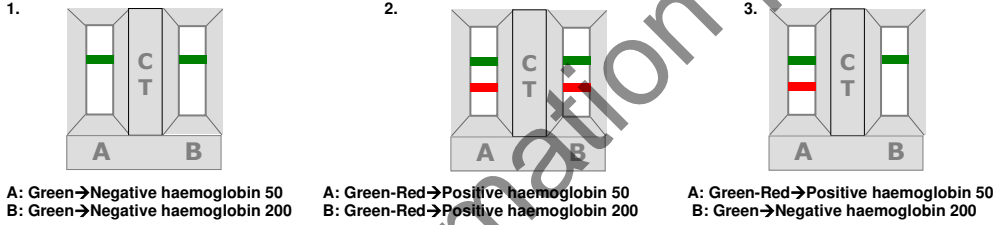
Add 3 drops in B-circular window.



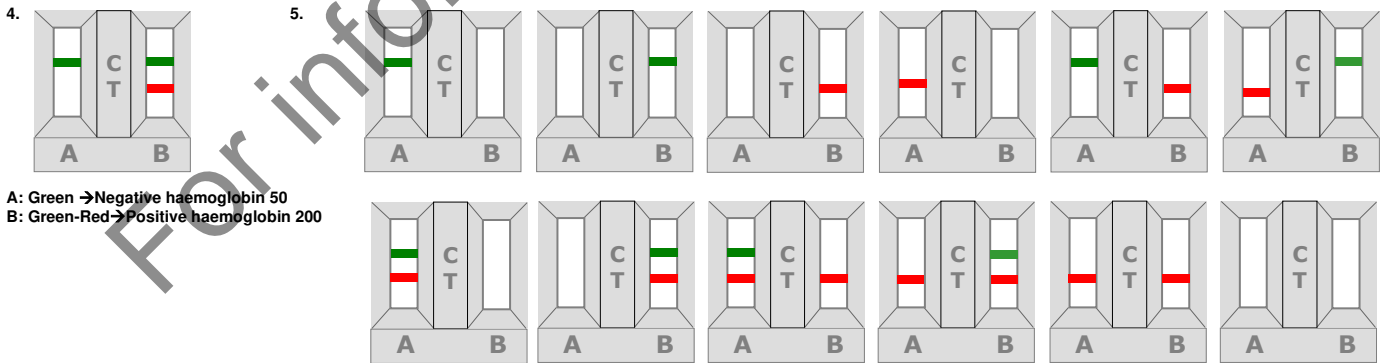
(5)

(6)

INTERPRETATION OF THE RESULTS (please refer to the illustration below)



INVALID RESULTS



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	A (Haemoglobin 50 (concentration ≥ 50 ng/mL))	B (Haemoglobin 200 (concentration ≥ 200 ng/mL))	Interpretation of the results
1.	- GREEN	- GREEN	There is no human haemoglobin presence. Haemoglobin marker is not present in patient sample (<50ng/mL), which might mean no faecal occult blood and no gastrointestinal bleeding.
2.	+ GREEN-RED	+ GREEN-RED	High haemoglobin concentration (≥ 200 ng/mL) is present in patient sample, which might mean some gastrointestinal bleeding problem (e.g. caused by colorectal cancer, bacterial infections, inflammatory bowel disease, etc.). Additional confirmatory diagnostic (endoscopy) should be followed up to determine the exact cause and source of the blood.
3.	+ GREEN-RED	- GREEN	Haemoglobin marker is present in patient sample (≥ 50 ng/mL and <200ng/mL), which might mean small amounts of blood loss near the detection limit of the combo test. If the problem still persists, physician should evaluate all clinical and laboratory findings.
4.	- GREEN	+ GREEN-RED	Invalid result. If B is positive, A has to be also positive.
5.	Any other result	Any other result	Invalid result either A or B, we recommend repeating the assay using the same sample with another test.

INVALID: Total absence of any control coloured line (GREEN) regardless the appearance or not of the result lines (RED). Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are mostly the main reasons for control lines failure. Review the procedure and repeat the assay using a new test. If the symptoms or situation still persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red coloured bands in the test lines (T) in the results windows will vary depending on the concentration of human haemoglobin present in the specimen.

QUALITY CONTROL

Internal procedural controls are included in the test. The green lines appearing in the control lines (C) in the results windows are internal controls, which confirm sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. The test must be carried out within 2 hours after opening of the sealed bag.
2. An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
3. The intensity of test line may vary from very strong at high haemoglobin concentration to faint when the haemoglobin concentration is close to the cut-off value of the test.
4. CerTest FOB 50+200 should be used only with samples from human faeces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper faecal specimens must be obtained
5. Positive results determine the presence of human haemoglobin in faecal samples; nevertheless, it can be due to several causes, besides colorectal bleeding, such as haemorrhoid, blood in urine or stomach irritations. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the blood in the stool.
6. A negative result is not meaningful because of it is possible the haemoglobin concentration in the stool sample is lower than the cut-off values. Negative results do not exclude bleeding, as some polyps and colorectal cancers may bleed intermittently or not during certain stages of the disease. Moreover, blood may not be uniformly distributed in stool samples.
7. This test may be less sensitive for detecting upper gastrointestinal bleeding because blood degrades as it passes through the gastrointestinal tract.
8. Patients should not collect samples during their menstrual period, if they have bleeding haemorrhoids, blood in urine, or if they have strained during bowel movement.
9. Mucous stool samples may cause non-specific reactions in the test. Every mucous stool sample whose result is positive should be followed up with other techniques of diagnosis to confirm the result.
10. Faecal samples whose antigen concentration is near to the cut-off value of the CerTest FOB 50+200 test could be lost if the sample has been diluted and preserved until 2 days at room temperature or until 5 days at 2-8°C until to be tested. For faecal samples near to the detection limit value is better to dilute the sample and make immediately the test.

EXPECTED VALUES

Some studies established 200ng haemoglobin/mL as optimal cut-off value in faecal occult blood test used in colorectal cancer screening programs.

Colorectal cancer affects both men and women of all racial and ethnic groups, being most often found in people aged 50 years or older. Regarding men, colorectal cancer is the third most common cancer after prostate and lung cancers. Regarding women, colorectal cancer is the third most common cancer after breast and lung cancers.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

Cut-off values of CerTest FOB 50+200 are 50ng/mL (5.1µg hHb/g faeces) for strip A and 200ng/mL (20µg hHb/g faeces) for strip B.

Clinical sensitivity and specificity

An evaluation with faecal samples was performed comparing the results obtained by an immunochromatographic test (CerTest FOB 50+200, CerTest) and an ELISA test (Human Hemoglobin ELISA kit, ICL).

The results were as follows:

Data for cut-off value 5 µg hHb/g (Strip A: FOB 50)

		ELISA test: Human Hemoglobin ELISA kit		
		+	-	Total
IC test: CerTest FOB 50+200 (Strip A: FOB 50)	+	38	11	49
	-	0	49	49
	Total	38	60	98

CerTest FOB 50+200 (Strip A: FOB 50) vs Human Hemoglobin ELISA kit		
	Mean Value	95% confidence interval
Sensitivity	100.0%	90.7– 100.0%
Specificity	81.7%	69.6 – 90.5%
PPV	77.6%	63.4 - 88.2%
NPV	100.0%	92.7 – 100.0%

Specificity for a cut-off of 1µg hHb/g: 93.5% (mean value); 82.1-98.6% (95% confidence interval).

Data for cut-off value 20 µg hHb/g (Strip B: FOB 200)

		ELISA test: Human Hemoglobin ELISA kit		
		+	-	Total
IC test: CerTest FOB 50+200 (Strip B: FOB 200)	+	26	10	36
	-	1	61	62
	Total	27	71	98

CerTest FOB 50+200 (Strip B: FOB 200) vs Human Hemoglobin ELISA kit		
	Mean Value	95% confidence interval
Sensitivity	96.3%	81.0 – 99.9%
Specificity	85.9%	75.6 – 93.0%
PPV	72.2%	54.8 - 85.8%
NPV	98.4%	91.3 –100.0%

Specificity for a cut-off of 5µg hHb/g: 98.3% (mean value); 91.1-100.0% (95% confidence interval).

The results showed a high sensitivity and specificity to detect human haemoglobin using CerTest FOB 50+200.

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Cross-Reactivity

An evaluation was performed to determine the cross reactivity of CerTest FOB 50+200; no cross reactivity against other gastrointestinal pathogens, other organism, substances and/or faecal markers occasionally present in faeces:

<i>Adenovirus</i>	<i>Clostridium perfringens</i>	Human lactoferrin	<i>Salmonella typhi</i>
<i>Astrovirus</i>	<i>Cryptosporidium</i>	Human transferrin	<i>Salmonella typhimurium</i>
Bovine haemoglobin	<i>Entamoeba dispar</i>	<i>Legionella pneumophila</i>	<i>Shigella boydii</i>
Bovine transferrin	<i>Entamoeba histolytica</i>	<i>Listeria monocytogenes</i>	<i>Shigella dysenteriae</i>
Bovine lactoferrin	<i>Escherichia coli</i> O111	<i>Norovirus GI</i>	<i>Shigella flexneri</i>
<i>Campylobacter coli</i>	<i>Escherichia coli</i> O26	<i>Norovirus GII</i>	<i>Shigella sonnei</i>
<i>Campylobacter jejuni</i>	<i>Escherichia coli</i> O157	Pig haemoglobin	<i>Streptococcus pneumococcal</i>
<i>Clostridium difficile</i> antigen GDH	<i>Giardia</i>	<i>Rotavirus</i>	<i>Streptococcus pyogenes</i>
<i>Clostridium difficile</i> Toxin A	<i>Helicobacter pylori</i>	<i>Salmonella enteritidis</i>	<i>Yersinia enterocolitica</i> O:3
<i>Clostridium difficile</i> Toxin B	Human calprotectin	<i>Salmonella paratyphi</i> A	<i>Yersinia enterocolitica</i> O:9

No special diet is recommended prior to testing. There are not interferences with any foods (Vitamin C, broccoli, carrots...).

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ESPAÑOL**USO PREVISTO**

CerTest FOB 50+200 combo card es una prueba inmunocromatográfica (test cualitativo de cut-off) de un solo paso para la determinación cualitativa de hemoglobina humana (hHb) en muestras de heces, presentando unos valores de cut-off para A: 50ng/mL y para B: 200ng/mL.

CerTest FOB 50+200 combo card ofrece un ensayo de cribado sencillo, de alta sensibilidad y no invasivo para realizar un diagnóstico presuntivo de sangrado gastrointestinal (ej. causado por cáncer colorrectal).

INTRODUCCIÓN

El cáncer colorrectal es la segunda causa principal de enfermedad y muerte en el mundo occidental. El cribado o screening, cuando se usan los tests de sangre oculta en heces, está basado en la detección de sangrado en heces; síntoma importante de los neoplasmas del colon, el cáncer en su etapa inicial y los pólipos adenomatosos del intestino. El cáncer colorrectal también está asociado con una reacción inflamatoria local y aguda que en algunos casos puede determinarse mediante la detección de neutrófilos (glóbulos blancos).

La hemoglobina es una proteína de los glóbulos rojos que contiene hierro y cuya función es transportar el oxígeno en todos los vertebrados. Puede ser liberada en el tracto gastrointestinal y eliminada a través de las heces, en las enfermedades asociadas a un sangrado gastrointestinal.

FUNDAMENTO DEL TEST

CerTest FOB 50+200 combo card es una prueba cualitativa de cut-off inmunocromatográfica para la detección de hemoglobina humana en muestras de heces.

Tira A consiste en una membrana de nitrocelulosa fijada previamente con anticuerpos monoclonales de ratón frente a hemoglobina humana en la línea de test (T), en la ventana de resultados, y en la línea de control (C), con anticuerpos policlonales de conejo frente a una proteína específica. En el material absorbente para la muestra se ha dispensado una preparación de reactivos para la línea de test (anticuerpos monoclonales de ratón frente a hemoglobina humana) conjugada con látex de poliestireno rojo y otra preparación para la línea de control (proteína específica de unión) conjugada con látex de poliestireno verde, formando dos complejos coloreados conjugados.

Tira B consiste en una membrana de nitrocelulosa fijada previamente con anticuerpos monoclonales de ratón frente a hemoglobina humana en la línea de test (T), de la ventana de resultados, y en la línea de control (C), con anticuerpos policlonales de conejo frente a una proteína específica. En el material absorbente para la muestra se ha dispensado una preparación de reactivos para la línea de test (anticuerpos monoclonales de ratón frente a hemoglobina humana) conjugada con látex de poliestireno rojo y otra preparación para la línea de control (proteína específica de unión) conjugada con látex de poliestireno verde, formando dos complejos coloreados conjugados.

Si la muestra es hemoglobina humana positiva, los antígenos de la muestra diluida reaccionan con el complejo conjugado coloreado rojo (anticuerpos monoclonales anti-hemoglobina humana -microesferas rojas de látex) en la tira A, y si la muestra es hemoglobina humana positiva, los antígenos de la muestra diluida de heces reaccionan con el complejo conjugado coloreado rojo (anticuerpos monoclonales anti-hemoglobina humana -microesferas rojas de látex) en la tira B, los cuales fueron secados previamente en el material absorbente. Esta mezcla avanza por capilaridad a través de la membrana. Conforme la muestra va migrando también lo hacen los complejos conjugados. Los anticuerpos anti-hemoglobina humana presentes en la membrana de la tira A (línea de test) y los anticuerpos anti-hemoglobina humana presentes en la membrana de la tira B (línea de test) capturarán el complejo coloreado del test y la línea roja aparecerá en ambas tiras. Estas líneas se usarán para interpretación del resultado.

Si la muestra es negativa, no hay presencia de hemoglobina humana o los antígenos se encuentran en una concentración inferior al valor de cut-off y no se produce reacción con ningún complejo coloreado rojo. Los anticuerpos anti-hemoglobina humana presentes en las membranas (líneas de test) no capturarán el antígeno-complejo coloreado rojo (no formado) y no aparecerán las líneas rojas.

Independientemente de que la muestra sea positiva o no, la mezcla continuará moviéndose a través de las membranas hacia los anticuerpos inmovilizados frente a la proteína específica localizados en las líneas de control. Estos anticuerpos anti-proteína específica presentes en ambas membranas capturarán el complejo conjugado de control y las líneas de control verdes siempre aparecerán. La aparición de estas líneas se utiliza: 1) para verificar que se ha añadido el volumen de muestra suficiente, 2) que el flujo ha sido apropiado y 3) como control interno de los reactivos.

CONDICIONES DE ALMACENAMIENTO

El producto debe ser almacenado entre 2 y 30° C en su envase original sellado, para conseguir un óptimo funcionamiento hasta la fecha de caducidad impresa en el envase. No debe abrirse hasta el momento de su uso. No congelar.

PRECAUCIONES

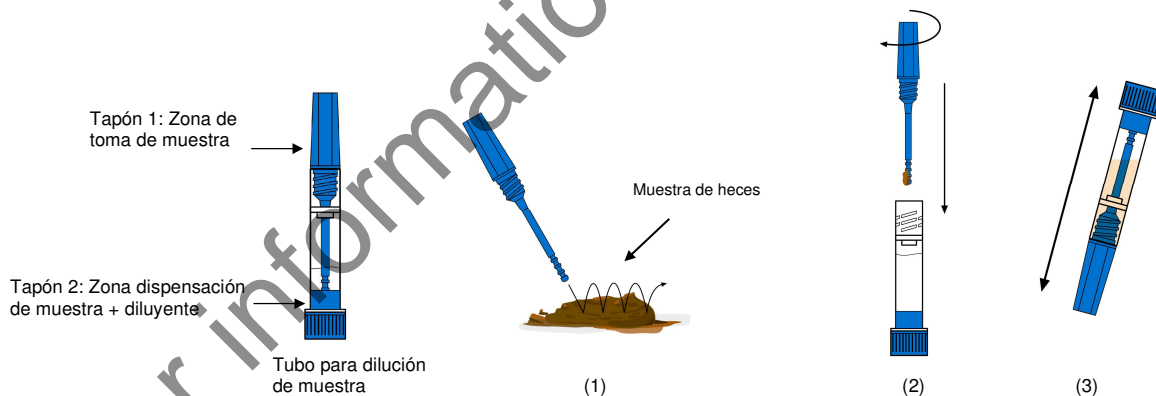
- Sólo para uso profesional *in vitro*.
- No utilizar después de la fecha de caducidad.
- Las muestras se deben considerar potencialmente peligrosas y deben ser manipuladas de la misma forma que a un agente infeccioso. Un nuevo test deberá ser usado para cada muestra para evitar errores de contaminación.
- Los tests usados deben ser gestionados como residuos sanitarios (contenedor de residuos sanitarios).
- Los reactivos contienen conservantes. Debe evitarse cualquier contacto con la piel o las mucosas. Consultar fichas de seguridad, disponibles bajo petición.
- Los componentes proporcionados con el kit son aprobados para su uso con CerTest FOB 50+200 test. No se deben usar con componentes de otros kits comercializados.
- La presencia de líneas amarillentas en la ventana de resultados (zona línea de control y zona línea de test), antes de utilizar el test, es completamente normal y no supone fallo de funcionalidad del test.
- Seguir las Buenas Prácticas de Laboratorio, llevar ropa de protección adecuada, usar guantes desechables, gafas de protección y mascarilla. No comer, ni beber o fumar en la zona de trabajo.

RECOGIDA DE MUESTRAS Y PREPARACIÓN

Las muestras deben ser recogidas en un recipiente limpio. Las muestras se deben conservar en frío (2-8° C) máximo durante 7 días hasta el momento de utilizarlas. Para conservar las muestras durante un tiempo prolongado, como máximo 6 meses, deben mantenerse congeladas a -20°C. En este caso, la muestra debe descongelarse totalmente y alcanzar la temperatura ambiente para poder utilizarla en la prueba. Homogenizar la muestra vigorosamente antes de su preparación.

Preparación de la muestra (ver dibujo):

1. Abrir el tapón 1 del tubo para dilución de muestra y con ayuda del palito tomar suficiente cantidad de muestra de las heces recogidas. Para ello se debe introducir el palito una sola vez en 4 zonas distintas de la muestra (1), asegurándose de que, en cada inserción, la hélice del palito se cubra con la muestra para tomar la cantidad adecuada de heces. A continuación, introducir la muestra en el tubo para dilución de muestra (2). Para muestras líquidas, añada aprox. 20µL en el tubo para dilución de muestra utilizando una micropipeta.
2. Cerrar el tubo que contiene la muestra y el diluyente (2). Agitarlo para facilitar la dispersión de la muestra (3). Este tubo que contiene la muestra diluida puede conservarse durante 2 días a temperatura ambiente o en frío (2-8°C) durante 5 días antes de realizar la prueba.



Precauciones: No se deben obtener muestras de pacientes durante su periodo menstrual, si presentan hemorroides sangrantes, sangre en orina, o estreñimiento.

MATERIALES
MATERIALES SUMINISTRADOS

- CerTest FOB 50+200 combo card tests
- Instrucciones de uso
- Tubos para dilución de muestra con diluyente

MATERIALES NECESARIOS NO SUMINISTRADOS

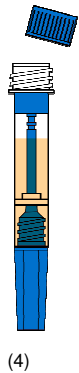
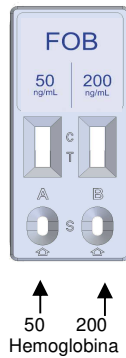
- Recipiente para recogida de muestras
- Guantes desechables
- Cronómetro

PROCEDIMIENTO

Previamente los tests, las muestras de heces y los controles se deben acondicionar a la temperatura ambiente (15-30° C). No abrir los envases hasta el momento de la prueba.

1. Agitar el tubo para dilución de muestra para asegurar una buena dispersión.
2. Sacar el test CerTest FOB 50+200 de su envase antes de utilizarlo.
3. Tomar el tubo para dilución de muestra, abrir el tapón 2 (4) y añadir 3 gotas en la ventana circular marcada con la letra A (5), y añadir 3 gotas del líquido, con el mismo tubo, en la ventana circular marcada con la letra B (6), evitando añadir partículas sólidas con el líquido.
4. **Leer el resultado a los 10 minutos.** No leer el resultado superados los 10 minutos.

Si se da el caso de que el test no funciona debido a la presencia de partículas sólidas, agitar con el palito la muestra en la ventana (S). Si no funciona, añadir una gota de diluyente hasta que se vea avanzar el líquido por la zona de resultados.



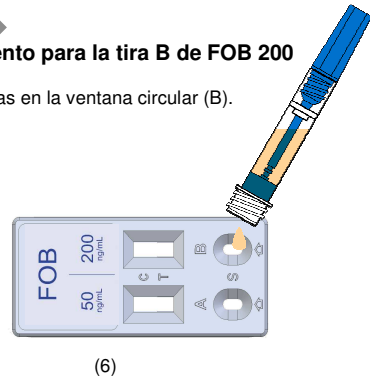
Procedimiento para la tira A de FOB 50

Añadir 3 gotas en la ventana circular (A).

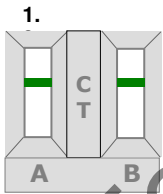


Procedimiento para la tira B de FOB 200

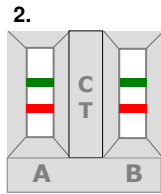
Añadir 3 gotas en la ventana circular (B).



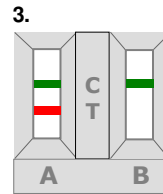
INTERPRETACION DE RESULTADOS (por favor, fíjese en el siguiente dibujo)



A: Verde→Negativo Hemoglobina 50
B: Verde→Negativo Hemoglobina 200

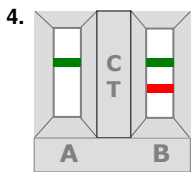


A: Verde-Rojo→Positivo Hemoglobina 50
B: Verde-Rojo→Positivo Hemoglobina 200

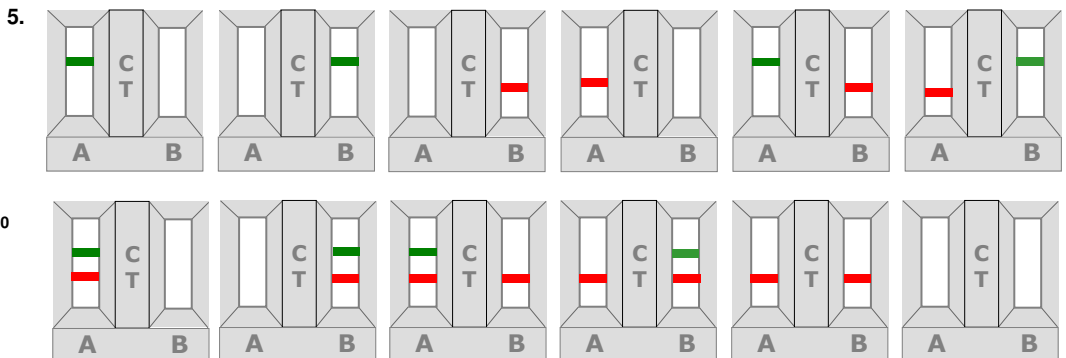


A: Verde-Rojo→Positivo Hemoglobina 50
B: Verde→Negativo Hemoglobina 200

RESULTADOS INVÁLIDOS



A: Verde→Negativo Hemoglobina 50
B: Verde-Rojo→Positivo Hemoglobina 200



	A (Hemoglobina 50 (concentración ≥ 50 ng/mL))	B (Hemoglobina 200 (concentración ≥ 200 ng/mL))	Interpretación de los resultados
1.	- VERDE	- VERDE	El marcador hemoglobina no está presente en la muestra del paciente. No hay presencia de marcadores de hemoglobina en la muestra del paciente (o están en concentración < 50 ng/mL), puede significar que no hay sangrado gastrointestinal (no hay sangre oculta en heces).
2.	+ VERDE-ROJO	+ VERDE-ROJO	El marcador hemoglobina (≥ 200 ng/mL) está presente con una concentración alta en la muestra del paciente: podría significar que se trata de un problema de sangrado gastrointestinal (debido a cáncer colorrectal, infecciones bacterianas o enfermedades inflamatorias del intestino). Se debería realizar un diagnóstico confirmatorio (endoscopia) para poder determinar la causa y origen de esta presencia de sangre.
3.	+ VERDE-ROJO	- VERDE	El marcador hemoglobina está presente en la muestra del paciente (≥ 50 ng/mL y < 200 ng/mL), podría significar que hay presencia de una pequeña cantidad de pérdida de sangre cercana al límite de detección del combo test. Si el problema persistiese, el médico debería realizar una evaluación de los resultados clínicos y de laboratorio obtenidos.
4.	- VERDE	+ VERDE-ROJO	Resultado inválido. Si B es positivo, A debe ser positivo también.
5.	Cualquier otro resultado	Cualquier otro resultado	Resultado inválido. Cualquier resultado inválido en A o en B, se recomienda repetir la prueba con la misma muestra y otro test.

INVÁLIDO: Cuando alguna línea de control (VERDE) no aparece, independientemente de que aparezcan o no las líneas de test (ROJA). Las causas más comunes por las que puede aparecer un resultado inválido son: un volumen insuficiente de muestra, una forma de proceder incorrecta o un deterioro de los reactivos. Si ocurriera esto, debe revisar el procedimiento y repetir la prueba con un nuevo test. Si los síntomas o la situación persisten, debe dejar de utilizar la prueba y contactar con su distribuidor.

OBSERVACIONES

La intensidad de las líneas de color rojo en la zona de test (T) en la ventana de resultados variará dependiendo de la concentración de hemoglobina humana presente en la muestra.

CONTROL DE CALIDAD

Los controles internos de funcionamiento vienen incluidos en la prueba. Las líneas verdes que aparecen en las líneas de control (C) en las ventanas de resultados son los controles internos del proceso, comprobando que el volumen de muestra es suficiente y que el procedimiento seguido ha sido el adecuado.

LIMITACIONES

- Una vez abierto el envase, el test no debe usarse después de 2 horas.
- Un exceso de muestra de heces puede dar resultados erróneos, dando líneas no muy definidas de color pardo, que no tienen ningún valor diagnóstico. Diluir la muestra con el diluyente y repetir el test.
- La intensidad de la línea de test puede variar desde muy fuerte a alta concentración de hemoglobina humana a débil cuando la concentración de hemoglobina humana está cerca del valor de cut-off del test.
- CerTest FOB 50+200 debería utilizarse sólo con muestras de heces humanas. El uso de otras muestras no ha sido determinado. La calidad del test depende de la calidad de la muestra; por lo que se debe realizar una adecuada toma de muestras fecales.
- Los resultados positivos determinan la presencia de hemoglobina humana en muestras de heces; sin embargo, ésta puede ser debida a varias causas, como hemorroides, sangre en orina, o irritaciones estomacales. Un resultado positivo debería ser contrastado con otras técnicas diagnósticas para determinar la fuente y la causa de la presencia de sangre en la muestra de heces.
- Un resultado negativo no se debe considerar como concluyente, puede darse que la concentración de hemoglobina humana en la muestra de heces sea inferior a los valores de cut-off. Resultados negativos no excluyen las hemorragias causadas por algunos pólipos ni el cáncer colorrectal, ya que pueden provocar hemorragias de forma intermitente o no provocarlas durante alguna fase de la enfermedad. Además, la sangre podría no haberse distribuido de manera uniforme en la muestra de heces.
- Este test puede ser menos sensible para detectar hemorragias del tracto gastrointestinal superior porque la sangre se va degradando a través del mismo hasta ser expulsada junto con las heces.
- No se deben obtener muestras de pacientes durante su periodo menstrual, si presentan hemorroides sangrantes, sangre en orina, o estreñimiento.

CERTEST FOB 50+200

*One Step test to detect haemoglobin (50 ng/mL and 200 ng/mL) in combo card format /
Prueba combo de un solo paso para detección de hemoglobina (50 ng/mL y 200 ng/mL) en formato cassette.*

9. Muestra de heces mucosas podrían provocar reacciones inespecíficas en el test. Toda muestra de heces mucosas cuyo resultado sea positivo debería ser contrastado con otras técnicas diagnósticas para confirmar el resultado.
10. Muestras de heces cuya concentración de antígeno esté cerca del valor de cut-off de CerTest FOB 50+200 podrían llegar a perderse si la muestra ha sido diluida y conservada hasta 2 días a temperatura ambiente o hasta 5 días a 2-8°C antes de ser probada. Para las muestras de heces cercanas al valor de cut-off del test es mejor diluir la muestra y realizar el test inmediatamente.

VALORES ESPERADOS

En varios estudios se ha determinado que el valor óptimo de cut-off de hemoglobina humana en heces es 200ng/mL para los test de detección de sangre oculta en heces para su uso en programas de cribado de detección de cáncer.

El cáncer colorrectal afecta tanto a hombres como a mujeres pertenecientes a todos los grupos raciales, aunque con mayor incidencia en personas a partir de los 50 años y en ancianos. En los hombres, supone la tercera causa más común de cáncer tras el de próstata y pulmón. En las mujeres, el cáncer colorrectal es la tercera causa de cáncer tras el de mama y pulmón.

CARACTERÍSTICAS DEL TEST

Sensibilidad analítica

El valor de cut-off de CerTest FOB 50+200 es 50ng/mL (5.1µg hHb/g heces) para Tira A and 200ng/mL (20µg hHb/g heces) para Tira B.

Sensibilidad y Especificidad Clínica

Se llevó a cabo una evaluación, con muestras de heces, comparando los resultados obtenidos por un test inmunocromatográfico (CerTest FOB 50+200, CerTest) y un test ELISA (Human Hemoglobin ELISA kit, ICL).

Los resultados se muestran a continuación:

Datos para valor de cut-off 5 µg hHb/g (Tira A: FOB 50)

		ELISA test: Human Hemoglobin ELISA kit		
		+	-	Total
IC test: CerTest FOB 50+200 (Tira A: FOB 50)	+	38	11	49
	-	0	49	49
	Total	38	60	98

CerTest FOB 50+200 (Tira A: FOB 50) vs Human Hemoglobin ELISA kit		
	Valor Medio	95% Intervalo de confianza
Sensibilidad	100.0%	90.7– 100.0%
Especificidad	81.7%	69.6 – 90.5%
VPP	77.6%	63.4 - 88.2%
VPN	100.0%	92.7 – 100.0%

Especificidad para un valor de cut-off de 1µg hHb/g: 93.5% (valor medio); 82.1-98.6% (95% intervalo de confianza).

Datos para valor cut-off 20 µg hHb/g (Tira B: FOB 200)

		ELISA test: Human Hemoglobin ELISA kit		
		+	-	Total
IC test: CerTest FOB 50+200 (Tira B: FOB 200)	+	26	10	36
	-	1	61	62
	Total	27	71	98

CERTEST FOB 50+200

One Step test to detect haemoglobin (50 ng/mL and 200 ng/mL) in combo card format /
Prueba combo de un solo paso para detección de hemoglobina (50 ng/mL y 200 ng/mL) en formato cassette

CerTest FOB 50+200 (Tira B: FOB 200) vs Human Hemoglobin ELISA kit		
	Valor Medio	95% Intervalo de confianza
Sensibilidad	96.3%	81.0 – 99.9%
Especificidad	85.9%	75.6 – 93.0%
VPP	72.2%	54.8 - 85.8%
VPN	98.4%	91.3 –100.0%

Especificidad para un valor de cut-off of 5µg hHb/g: 98.3% (valor medio); 91.1-100.0% (95% intervalo de confianza).

Los resultados mostraron que CerTest FOB 50+200 presenta una alta sensibilidad y especificidad para detectar hemoglobina humana.

Reacciones cruzadas

Se realizó una evaluación para determinar posibles reacciones cruzadas de CerTest FOB 50+200; no se detectó reacción cruzada con otros patógenos gastrointestinales, otros organismos, sustancias y/o marcadores fecales ocasionalmente presentes en las heces:

<i>Adenovirus</i>	<i>Entamoeba dispar</i>	<i>Lactoferrina humana</i>	<i>Shigella boydii</i>
<i>Astrovirus</i>	<i>Entamoeba histolytica</i>	<i>Legionella pneumophila</i>	<i>Shigella dysenteriae</i>
<i>Calprotectina humana</i>	<i>Escherichia coli O111</i>	<i>Listeria monocytogenes</i>	<i>Shigella flexneri</i>
<i>Campylobacter coli</i>	<i>Escherichia coli O26</i>	<i>Norovirus GI</i>	<i>Shigella sonnei</i>
<i>Campylobacter jejuni</i>	<i>Escherichia coli O157</i>	<i>Norovirus GII</i>	<i>Streptococcus pneumococcal</i>
<i>Clostridium difficile antigen GDH</i>	<i>Giardia</i>	<i>Rótavirus</i>	<i>Streptococcus pyogenes</i>
<i>Clostridium difficile Toxin A</i>	<i>Helicobacter pylori</i>	<i>Salmonella enteritidis</i>	<i>Transferrina bovina</i>
<i>Clostridium difficile Toxin B</i>	<i>Hemoglobina bovina</i>	<i>Salmonella paratyphi A</i>	<i>Transferrina humana</i>
<i>Clostridium perfringens</i>	<i>Hemoglobina de cerdo</i>	<i>Salmonella typhi</i>	<i>Yersinia enterocolitica O:3</i>
<i>Cryptosporidium</i>	<i>Lactoferrina bovina</i>	<i>Salmonella typhimurium</i>	<i>Yersinia enterocolitica O:9</i>

No se recomienda ninguna dieta especial antes de realizar el test. No presenta interferencias con ningún alimento (Vitaminas C, brócoli, zanahorias...).

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SYMBOLS FOR IVD COMPONENTS AND REAGENTS/

SÍMBOLOS PARA REACTIVOS Y PRODUCTOS PARA DIAGNÓSTICO IN VITRO

IVD In vitro diagnostic device Producto para diagnóstico in vitro	Keep dry Almacenar en lugar seco	Use by Fecha de caducidad	Manufacturer Fabricante	LOT Batch code Número de lote
Consult instructions for use Consultar las instrucciones de uso	Temperature limitation Limitación de temperatura	Contains sufficient for <n> test Contiene <n> test	DIL Sample diluent Diluyente de muestra	REF Catalogue number Número de referencia
Do not re-use No reutilizar	CE CE marking/ Marcado CE			

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