



**DEKLARACJA ZGODNOŚCI UE/
EU DECLARATION OF CONFORMITY**



DANE DOTYCZĄCE PRODUCENTA/ MANUFACTURER DETAILS	
Producent/ Manufacturer	Graso Zenon Sobiecki
Adres producenta/ Adress	Krag 4A 83-200 Starogard Gdański
Numer rejestracyjny producenta/ Manufacturer's registration number	PL-MF-000022437
DANE DOTYCZĄCE WYROBU/ DEVICE DETAILS	
Nazwa produktu/ Product name	CHROMagar C. difficile
Numer katalogowy/ Article number	1408PD90
Basic UDI-DI	590470801172PD90NL
Klasa ryzyka wyrobu, wg reguły/ Risk class and classification rule	klasa B wg Załącznika VIII, reguła 6 / class B acc. to the Annex VIII, rule 6
Ocena zgodności/ Conformity assessment	wg załącznika IX / acc. to Annex IX
DANE DOTYCZĄCE JEDNOSTKI NOTYFIKOWANEJ/ NOTIFIED BODIES DETAILS	
Nazwa jednostki notyfikowanej/ Name of the Notified Bodies	-
Numer identyfikacyjny jednostki notyfikowanej/ Notified Bodies ID number	-
Numer wydanego certyfikatu/ Certificate of conformity number	obowiązek spełnienia wymagania od 26.05.2027 r. obligation to meet the requirement since 26.05.2027 r.
Data ważności wydanego certyfikatu/ Certificate expiration date	obowiązek spełnienia wymagania od 26.05.2027 r. obligation to meet the requirement since 26.05.2027 r.
OŚWIADCZENIE PRODUCENTA/ MANUFACTURER STATEMENT	
Producent Graso Zenon Sobiecki z siedzibą firmy w miejscowości Krag 4A, 83-200 Starogard Gdański na swoją wyłączną odpowiedzialność oświadcza, że: wyżej wymienione produkty spełniają wymagania Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/746 z 5 kwietnia 2017r. w sprawie wyrobów medycznych do diagnostyki in vitro oraz uchylecia dyrektywy 98/79/WE i decyzji Komisji 2010/227/UE oraz wymagania Ustawy o wyrobach medycznych	

<p>z dnia 7 kwietnia 2022 r. Dokumentacja techniczna potwierdzająca zgodność wyrobu z powyższymi wymaganiami przechowywana jest w siedzibie producenta./</p> <p>The manufacturer Graso Zenon Sobiecki located in Krag 4A, 83-200 Starogard Gdański declares on his own responsibility that:</p> <p>the above-mentioned products meet the requirements of the Regulation of the European Parliament and of the Council (EU) 2017/746 of April 5, 2017. on in vitro diagnostic medical devices and repealing Directive 98/79 / EC and Commission Decision 2010/227/ EU and the requirements of the Medical Devices Act of April 7, 2022. . The technical documentation confirming the compliance of the product with the requirements of the Regulation is kept at the manufacturer's premises</p>
<p>ZASTOSOWANE WSPÓLNE SPECYFIKACJE, Z KTÓRYMI DEKLARUJE SIĘ ZGODNOŚĆ/ REFERENCES TO ANY COMMON SPECIFICATION USED AND IN RELATION TO WHICH CONFORMITY IS DECLARED</p>
<p>Producent posiada zintegrowany System Zarządzania Jakością zgodny z:</p> <p>The manufacturer implemented integrated quality management system in accordance with:</p>
<p><u>PN-EN ISO 9001</u> Systemy Zarządzania Jakością. Wymagania. / Quality Management System. Requirements.</p> <p><u>PN-EN ISO 13485</u> Wyroby medyczne. Systemy zarządzania jakością. Wymagania do celów przepisów prawnych. / Medical devices. Quality management systems. Requirements for regulatory purposes</p>
<p>DATA I MIEJSCE WYDANIA DEKLARACJI ZGODNOŚCI/ PLACE AND DATE OF ISSUE OF THE DECLARATION</p>
<p>17.06.2025r. Krag 4A,83-200 Starogard Gdański</p>
<p>DATA WAŻNOŚCI DEKLARACJI ZGODNOŚCI/ EXPIRATION DATE OF THE DECLARATION</p>
<p>26.05.2026r.</p>

Imię i nazwisko / Name : Zenon Sobiecki

Stanowisko / Position : Prezes firmy/ Company President



**DEKLARACJA ZGODNOŚCI UE/
EU DECLARATION OF CONFORMITY**



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Numer rejestracyjny producenta/ Manufacturer's registration number	PL-MF-000022437
DANE DOTYCZĄCE WYROBU/ DEVICE DETAILS	
Nazwa produktu/ Product name	Mueller Hinton II Agar + 5% Sheep Blood
Numer katalogowy/ Article number	1172PD90
Basic UDI-DI	590470801172PD90NL
Klasa ryzyka wyrobu, wg reguły/ Risk class and classification rule	klasa B wg Załącznika VIII, reguła 6 / class B acc. to the Annex VIII, rule 6
Ocena zgodności/ Conformity assessment	wg załącznika IX / acc. to Annex IX
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<p>z dnia 7 kwietnia 2022 r. Dokumentacja techniczna potwierdzająca zgodność wyrobu z powyższymi wymaganiami przechowywana jest w siedzibie producenta./</p> <p>The manufacturer Graso Zenon Sobiecki located in Krag 4A, 83-200 Starogard Gdański declares on his own responsibility that:</p> <p>the above-mentioned products meet the requirements of the Regulation of the European Parliament and of the Council (EU) 2017/746 of April 5, 2017. on in vitro diagnostic medical devices and repealing Directive 98/79 / EC and Commission Decision 2010/227/ EU and the requirements of the Medical Devices Act of April 7, 2022. . The technical documentation confirming the compliance of the product with the requirements of the Regulation is kept at the manufacturer's premises</p>
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Imię i nazwisko / Name : Zenon Sobiecki

Stanowisko / Position : Prezes firmy/ Company President

MUELLER HINTON II AGAR + 5% SHEEP BLOOD

INSTRUCTIONS FOR USE THE READY-TO-USE PLATED MEDIUM

1. Intended Use

Mueller Hinton II Agar + 5% Sheep Blood is a medium designed to test the drug susceptibility of fastidious bacteria by the disc diffusion method (Bauer-Kirby method), according to Clinical and Laboratory Standards Institute (CLSI) standards from isolated bacterial colonies from human clinical specimens.

The function of the medium to support diagnosis by determining the antimicrobial susceptibility/resistance profile of the fastidious bacteria isolated from clinical specimens.

Drug susceptibility profile used in the treatment of infections and the determination of the resistance mechanism of the pathogen detected in a clinical specimen enables to make the right, individual decision for the patient regarding the choice of an appropriate, effective antibiotic therapy.

The disk-diffusion method according to CLSI is based on the method described by the International Collaborative Study of Antimicrobial Susceptibility Testing in 1972. Due to its simplicity of performance this method is the most widely used method for testing bacterial drug susceptibility in medical laboratories. Correct, standardized performance of the test according to the CLSI method and obtaining reliable results require the use of this method without modification, including the use of the medium specified by CLSI.

According to CLSI procedures, Mueller Hinton II Agar + 5% Sheep Blood is a medium for determining the drug susceptibility profile of fastidious bacteria, especially the genus *Streptococcus*. Mueller Hinton II Agar + 5% Sheep Blood is recommended for testing antibiotic resistance of *Streptococcus pneumoniae* to: chloramphenicol, erythromycin, ofloxacin, tetracycline and vancomycin, in addition to screening for penicillin sensitivity.

Cat. no:	Substrate type:	Packaging:
1172PD90	Solid medium on a plate	1x10 pcs (90 mm)

2. Principle of procedure

Beef extract are sources of nitrogen, vitamins, carbon and amino acids. Starch absorbs toxic metabolic products. De-fibered sheep blood allows the growth of fastidious bacteria. Agar provides a solidifying agent.

Tests for microbial drug susceptibility should be performed by the disk-diffusion method in accordance with current CLSI recommendations.

The diffusion disc method is a method that utilizes the phenomenon in which a concentration gradient of an antimicrobial drug forms in a solid medium as a result of its diffusion from a blotting paper disc. As a result, the growth of microorganisms inoculated on the medium is inhibited around the disc. The measured diameter of the zone of inhibited growth, expressed in millimeters, is compared with the corresponding limit value specified in the relevant CLSI recommendations. As a result of this comparison, the test microorganism is classified into the appropriate susceptibility category to the specific antimicrobial drugs used in the test. In order to determine the mechanism of resistance, disks containing specific antibiotics/antimicrobial drugs are arranged on the medium. The characteristic size and shape of the zones of inhibition of bacterial growth on the medium makes it possible to determine the presence and type of resistance mechanism of the tested pathogen.

3. Medium composition

In g/1 distilled water:	Supplements/liter of medium:		
Casein peptone	17,5 g	Sheep blood	50 ml
Corn starch	1,5 g		
Beef extract	2,0 g		
Agar	17,0 g		

pH 7.3± 0.1 at 25° C.

Appearance of the medium – Homogeneous, red.

4. Medium preparation

The medium is ready to use. Bring the medium to room temperature immediately before use.

5. Equipment required, not provided

Equipment and reagents necessary for the test (e.g., saline, sterile swabs, antibiotic-soaked blotting disks) and general-laboratory equipment, including a densitometer or density standard, an incubator and a ruler or other system for measuring the size of inhibition zones.

6. Precautions

- The product is intended for professional use only.
- Non-automated product.
- The medium contains components of animal origin, which may be associated with the presence of biological pathogens, so the substrate should be handled in accordance with the rules for working with potentially infectious biological material.
- Do not use plates if the medium shows signs of microbial contamination, discoloration, drying, cracking or other signs of deterioration.
- Do not use damaged plates.
- Do not use plates after the expiration date.
- Re-incubation of previously inoculated plates is not allowed.
- To ensure correct test results, follow these instructions and the CLSI procedure.
- If the handling of the medium differs from that described in this manual, the laboratory is obliged to validate the procedure adopted.

7. Storage and shelf life

Store plates at 2-12°C until the expiration date. Store plates in their original packaging in an inverted position (agar side up), away from direct light sources. To avoid freezing of agar, do not store plates close to the refrigerator walls. To avoid the appearance of water condensation on the plate lid, do not open the refrigerator more often than necessary and do not store substrates in an overfilled refrigerator.

8. Expiration date

The medium stored at 2-12°C retains its properties up to 45 days from the date of production.

9. Specimens type

Use pure, fresh (about 16-24 hours old) cultures of pathogenic strains of fastidious bacteria isolated from human clinical specimens, or other samples inoculated onto solid media.

10. Test procedure

In order to ensure correct, reliable results of bacterial drug susceptibility testing by the disk-diffusion method, current CLSI procedures and guidelines must be strictly followed.

1. The medium should be brought to room temperature before use.

2. Preparation of inoculum. Prepare a suspension of the test strain at a density of 0.5 on the McFarland scale by suspending colonies of the strain in saline solution.

Collect colonies with a sterile loop or swab from non-selective medium, after 18-24 hours of culture.

Select a few morphologically similar colonies. Determine the density of the inoculum using a densitometer. The density of the suspension can also be determined by macroscopically comparing the density of the test strain's suspension with a 0.5 McFarland density standard. In this case, the turbidity of the test strain's suspension to the density standard should be compared on a white background with black stripes.

The prepared suspension of the test strain should be used within 15 minutes, but no later than 60 minutes after preparation.

3. Preparation of bacterial lawn. Dip a sterile cotton swab into the prepared suspension of the test strain. For Gram-negative bacteria, to avoid excessive inoculation, remove the excess suspension from the swab by pressing it against the inside of the tube, for Gram-positive bacteria, there is no need to press the swab against the inside of the tube. Plates can be inoculated manually or with an automatic inoculator. Spread the suspension evenly over the entire agar surface, making sure there are no gaps between each band, which is especially important for Gram-positive bacteria.

4. Apply antibiotic discs. Apply antibiotic discs to the agar surface. The discs should be applied to the medium within 15 minutes of inoculation. Press the discs lightly, as they should completely adhere to the agar surface. Once applied, the discs must not be moved, due to the rapid diffusion of the antibiotic from the disc into the medium. The number of discs on the plate should be limited so that the resulting zones of inhibition do not overlap and individual antibiotics do not interact with each other. A maximum of 6 antibiotic discs can be applied to a 90 mm diameter plate.

5. Incubation. Incubate inoculated plates under aerobic conditions at the temperature and for the time specified in CLSI procedures depending on the microorganism being tested. The plates should be inverted with the medium up, while making sure that the discs have not fallen off the agar surface. Incubation of the plates should begin within 15 minutes of applying the discs. The plates should not be incubated longer than recommended.

Detailed guidelines for the selection of antibacterial drugs and the performance of drug susceptibility testing by the disk-diffusion method are defined by current CLSI procedures.

11. Reading and interpretation

After the required incubation period, measure the size of the inhibition zones using a calibrated instrument such as a ruler or other measure device, or use automatic systems to measure of growth inhibition zone diameters. The measurement should be expressed in millimeters.

Interpret the obtained results of measuring of grown inhibition zones diameters in accordance with current CLSI guidelines.

When testing a pathogen for resistance mechanisms, the size and characteristic shape of the zones of bacterial inhibition for a particular type of resistance mechanism should be assessed.

12. Quality control

Perform medium quality control at a frequency and in a manner consistent with current CLSI guidelines for quality control of the disk-diffusion method and laboratory procedures.

Reference strains that ensure measurement consistency according to CLSI guidelines should be used to perform quality control tests.

13. Limitations of the method

- Due to variability in nutritional requirements, some strains may grow poorly or not at all on Mueller Hinton Agar II +5% Sheep Blood.
- Numerous factors can affect the diameters of inhibition zones and the results of the study.
- Numerous factors can affect the diameter of inhibition zones and the results of drug susceptibility testing, such as bacterial suspension density, growth rate, medium composition and pH.
- Drug susceptibility testing by the disk-diffusion method should be performed only with fresh, pure bacterial cultures.
- If the inoculum density is too high, it can reduce the zone of stunting, and if it is too low, it can increase the zones of stunting and cause difficulties in measuring them.
- Leaving inoculated plates at room temperature for longer than the recommended period before applying the discs may cause microbial proliferation, resulting in a decrease in the diameters of the zones of inhibition. Therefore, it is important to follow the 15-15-15 rule: the suspension should be used within 15 minutes of preparation, the discs should be applied within 15 minutes of plate inoculation, and plate incubation should be begin within 15 minutes of disc application.
- Improper storage of antibiotic discs can affect the stability of the antibiotics in them, which can reduce the diameter of inhibition zones and can be a source of interpretive errors in assessing the drug susceptibility of the pathogen under study.
- An important factor affecting the test result is how the stacks of plates are arranged in the incubator due to uneven heating. A maximum number of plates in a stack of 5 is recommended.
- Excessive shrinkage of the medium due to improper storage can lead to false results indicating the presence of sensitivity.
- Improper arrangement of antibiotic discs to test for the presence of resistance mechanisms may result in incorrect test results.

14. Characteristics of the method

Presented in CLSI documents and available literature.

15. Disposal of used material

Used and unused materials should be disposed of in accordance with current medical waste handling regulations and laboratory procedures for the disposal of infectious and potentially infectious materials.

16. Reporting of adverse events

According to current regulations, adverse events and incidents that can be directly related to the described medium must be reported to the manufacturer and to the competent authorities.

17. References




- Mueller and Hinton. 1941 Proc. Soc. Exp. Biol. Med. 48:330.
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- Murray, Baron, Jorgensen, Landry and Pfaller (eds.). 2007. manual of clinical microbiology, 9th ed. American Society for Microbiology, Washington, D.C..
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- Clinical and Laboratory Standards Institute. 2006 Approved standard: M2-A9. Performance standards for antimicrobial disk susceptibility tests, 9th ed. CLSI, Wayne, Pa.
- Clinical and Laboratory Standards Institute. 2008. performance standards for antimicrobial susceptibility testing; eighteenth informational supplement, M100-S18(M2). CLSI, Wayne, Pa.
- Thornsberry, Gavan and Gerlach. 1977. Cumitech 6, New developments in antimicrobial agent susceptibility testing. Coord. ed., Sherris. American Society for Microbiology, Washington, DC.
- World Health Organization. 1961. standardization of methods for conducting microbic sensitivity tests. Technical Report Series No. 210, Geneva, Switzerland.
- U.S. Food and Drug Administration. 2001. bacteriological analytical manual, online. AOAC International, Gaithersburg, Md.











History of document changes


Date of change	Section	Description of the change
2023/02/03	Entire document	Adaptation to the requirements of EU Regulation 2017/746

NOTE

The revision history of the document does not include editorial changes.

SYMBOL	NAME OF SYMBOL	DESCRIPTION	REF.
	Manufacturer	Indicates the medical device manufacturer.	5.1.1
	Date of manufacture	Indicates the date after which the medical device is not to be used.	5.1.3
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be used..	5.1.6

	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an invitro diagnostic medical device.	5.5.1
	Do not re-use	Indicates a medical device that is intended for one single use only.	5.4.2
	Contains sufficient for <n> tests	Indicates the total number of tests that can be performed with the medical device.	5.5.5
	Use -by date	Indicates the date after which the medical device is not to be used	5.1.4
	Temperature limit	Indicates the temperature limits of temperature shall be indicates adjacent to the upper and lower horizontal lines.	5.3.7
	Safety symbol (Compliance with EU requirements)	The CE marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European Union health, safety and environmental regulations.	nd.
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.	5.2.2
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	5.2.8

	Contains biological material of animal origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin	5.4.8
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83-211 Jabłowo



CHROMagar C. difficile

INSTRUCTIONS FOR USE THE READY-TO-USE PLATED MEDIUM

1. Intended use

CHROMagar C. difficile is a chromogenic medium for the qualitative detection and selective isolation of *Clostridioides difficile* bacteria in human stool specimens, and other specimens.

The function of CHROMagar C. difficile medium is to support the diagnosis of patients with symptoms indicative of potential *Clostridioides difficile* infection, as well as screening tests.

Clostridioides difficile is the cause of post-antibiotic pseudomembranous colitis, as well as milder diarrhea associated with antibiotic use. It is the cause of 25% cases of such diarrhea. These diseases occur most often in patients undergoing long-term broad-spectrum antibiotic therapy. Due to the destruction of a large part of the population of bacteria that make up the intestinal microbiome, that can occur because of prolonged use of antibiotics. This creates conditions optimal for proliferation of *C. difficile* strains, which may include toxigenic serotypes. *C. difficile* is usually found in small amounts as a component of the microbiome in about 3-5% of adults and in about 50% of infants, without causing any pathological symptoms in healthy conditions. Diseases caused by *C. difficile* usually are a result of nosocomial infections. These infections are usually endogenous, but can also be exogenous infections, occurring because of transmission of the toxigenic strain of the bacillus or its spores by medical personnel, or other patients

Cat. no:	Medium type:	Packaging:
1408PD90	solid medium on a plate	1x10 pcs (90 mm)

2. Principle of the procedure

Peptones with yeast extract provides a source of nitrogen and vitamins in CHROMagar C. difficile medium. The supplement mix inhibits the growth of most microorganisms present in the specimens other than *Clostridioides difficile*. Growth factors stimulate the growth of *Clostridioides difficile*. The chromogenic mix allows detection of *Clostridioides difficile*, causing it to form colourless colonies. In addition, *C. difficile* colonies are fluorescent under UV light of wavelength 365 nm.

3. Medium composition

In g/l distilled water:	Supplements/liter of medium
Peptones and yeast extract	25,0 g
Salts	9,0 g
Chromogenic mix	1,7 g
Growth factors	4,0 g
Agar	15,0 g
	Selective mix
	0,325 g

pH 7.8± 0.2 at 25° C.

Appearance of the medium – clear, straw.

4. Medium preparation

The medium is ready to use. Bring the medium to room temperature immediately before use.

5. Equipment required, not provided

Standard laboratory equipment required for testing, including an incubator or an atmosphere controlled incubator.

6. Precautions

- The product is intended for professional use only.
- Non-automated product.
- The medium contains components of animal origin, which may be associated with the presence of biological pathogens, therefore must be handled in accordance with principles of handling potentially infectious biological material.

- Do not use plates if the medium shows signs of microbial contamination, discoloration, drying, cracking or other signs of deterioration.
- Do not use damaged plates.
- Do not use plates after the expiration date.
- Re-incubation of previously inoculated plates is not allowed.
- To ensure correct results, follow these instructions.
- If the handling of the medium differs from that described in this manual, the laboratory is obliged to validate the procedure adopted.

7. Storage

Store plates at 2-12°C until the expiration date. Store plates in their original packaging, inverted position (agar side up), away from direct light sources. To avoid freezing of agar, do not store plates close to the refrigerator walls. To avoid appearance of water condensation on the plate lid, do not open the refrigerator more often than necessary and do not store plates in an overfilled refrigerator.

8. Expiration date

The medium stored at 2-12°C retains its properties up to 3 months from the date of production.

9. Specimen type

Human fresh stool specimens containing blood, rectal swabs, as well as other specimens of clinical materials. Place the specimen in an airtight, sterile container with a screw cap. Do not allow the stool to dry out. If the patient is unable to excrete stool, take a rectal swab specimen.

Deliver specimens for testing to the laboratory within 2 hours of collection. If it is not possible to deliver specimen to the laboratory within this time, it should be placed in Cary-Blair or Amies transport medium and refrigerated. At refrigerator temperature, specimens in transport medium are stable for up to 2 days.

10. Test procedure

1. Allow the medium to warm in room temperature before inoculation.
2. Inoculate the specimen by spreading it directly on the surface of the agar surface.
3. If the specimen was taken on a swab - gently rotate the tip of the swab on a small area of agar just around the edges of the plate, and then inoculate specimen using streak plate method with a sterile loop.
4. Incubate the inoculated plates under anaerobic conditions at 35±2°C.
5. Examine for growth after 24 hours of incubation.

11. Reading and interpretation

After incubation observe:

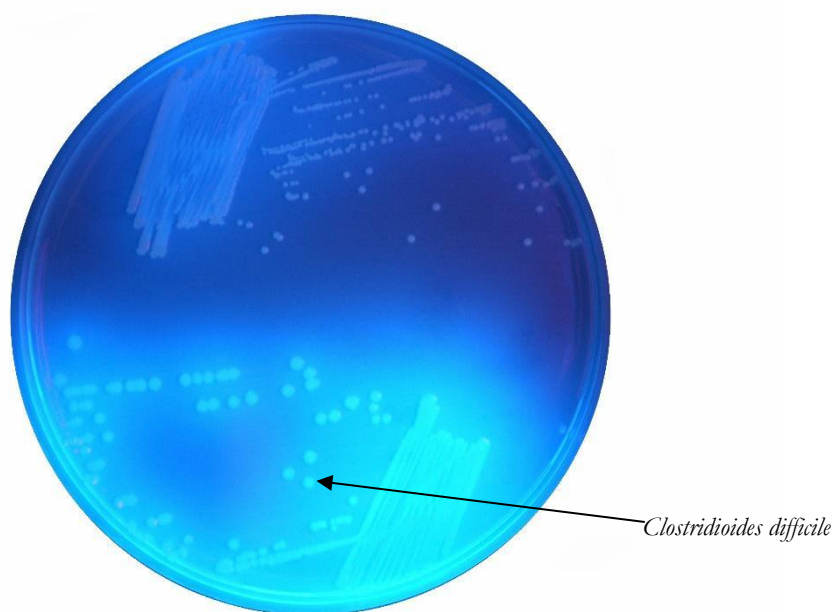
- Presence of growth,
- colony morphology,
- fluorescence of colonies under UV light of wavelength 365 nm.

Typical colony morphology on CHROMagar *C.difficile* medium:

Microorganism	Typical colony morphology
<i>C. difficile</i>	Colourless colonies, fluorescent under UV light
Most other bacteria	No growth
Gram-positive bacteria	No growth

Evaluating the fluorescence of colonies under UV light (365nm wavelength) increases the sensitivity of the procedure, as *Clostridioides difficile* bacteria exhibit the ability to fluoresce.

For the final identification of cultured microorganisms, additional tests and/or confirmatory tests should be carried out using other methods used in the laboratory.



Colony morphology and growth pattern of *Clostridioides difficile* using UV lamp on CHROMagar C.difficile

12. Quality control

The nutritional properties and selectivity of the medium should be checked using reference strains giving the expected positive and negative reactions. The test should be performed using pure, 18 – 24-hour cultures of reference strains giving the desired reactions. Use the following reference strains to perform medium quality control:

Reference strain:	Growth intensity:	Colonies morphology:
<i>Clostridium difficile</i> ATCC 9689	good growth	Colourless, fluorescent under UV light
<i>Bacteroides fragilis</i> ATCC 25285	no growth	-
<i>Staphylococcus aureus</i> ATCC 25923	no growth	-
<i>Clostridium perfringens</i> ATCC 13124	no growth	-

Other reference strains may be used in accordance with the laboratory's procedures and instructions. Quality control procedures should meet the requirements of applicable regulations and guidelines/recommendations.

13. Limitations of the method

- Due to variability in nutritional requirements, some strains of *Clostridioides difficile* may grow poorly or not at all on CHROMagar C.difficile medium.

14. Characteristics of the method

PCR has become the leading technique for detecting *C. difficile*. Nevertheless, culturing is essential for typing bacterial strains and determining their antibiotic susceptibility. CHROMagar *C. difficile* medium was designed to simplify and accelerate cultivation of these microorganisms, as well as to exhibit their fluorescent properties due to its composition. It is an extremely sensitive medium of high specificity.

The results of comparative studies indicates high sensitivity and specificity of CHROMagar *C. difficile* medium**, 2044 stool specimens were tested, incubation was conducted for 24 hours at 35°C in an anaerobic environment.

	CHROMagar C.difficile	Reference method (Taurocholate-CCFA medium)*.
Sensitivity	95,4% **	70%
Specificity	88,8% **	97%

* - taurocholate-CCFA (Cycloserine-Cefoxitin-Fructose-Egg Yolk) medium.

** - data obtained from the study "Comparison of CHROMagar™ C.difficile and taurocholate-CCFA media for isolation of toxigenic *Clostridium difficile* from stools", Gaillot O. et al. ASM 2014

15. Disposal of used material

Used and unused materials should be disposed of in accordance with current medical waste handling regulations and laboratory procedures for the disposal of infectious and potentially infectious materials.

16. Reporting of adverse events

According to current regulations, adverse events and incidents that can be directly linked to the described substrate must be reported to the manufacturer and to the competent authorities.

17. References





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History of document changes

Date of change	Section	Description of the change
2023/04/14	Entire document	Adaptation to the requirements of EU Regulation 2017/746

NOTE

The revision history of the document does not include editorial changes

SYMBOL	NAME OF SYMBOL	DESCRIPTION	REF.
	Manufacturer	Indicates the medical device manufacturer.	5.1.1
	Date of manufacture	Indicates the date after which the medical device is not to be used.	5.1.3
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be used..	5.1.6
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5

	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an invitro diagnostic medical device.	5.5.1
	Do not re-use	Indicates a medical device that is intended for one single use only.	5.4.2
	Contains sufficient for <n> tests	Indicates the total number of tests that can be performed with the medical device.	5.5.5
	Use -by date	Indicates the date after which the medical device is not to be used	5.1.4
	Temperature limit	Indicates the temperature limits of temperature shall be indicates adjacent to the upper and lower horizontal lines.	5.3.7
	Safety symbol (Compliance with EU requirements)	The CE marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European Union health, safety and environmental regulations.	nd.
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.	5.2.2
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	5.2.8
	Contains biological material of animal origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin	5.4.8



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