

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

**Контрольный материал качества Technopath Multi-CHECK Combi для анализатора
иммунофлюоресцентного AQT90 FLEX,
в следующих вариантах исполнения:**

1. Уровень 1 (AQT90 FLEX Technopath Multi-CHECK Combi Level 1 (MCCI1)):

- Пробирка с красным колпачком на 5 тестов – 6 шт.
- Вкладыш с характеристиками продукта на штрих-кодах - 1 шт.
- Инструкция – 1 шт.

2. Уровень 2 (AQT90 FLEX Technopath Multi-CHECK Combi Level 2 (MCCI2)):

- Пробирка с желтым колпачком на 5 тестов – 6 шт.
- Вкладыш с характеристиками продукта на штрих-кодах – 1 шт.
- Инструкция – 1 шт.

Производства

**Techno-path Manufacturing Ltd / Техно-пэт Мэнюфэкчуринг Лтд
Fort Henry Business Park, Ballina, Co. Tipperary, Ireland (Ирландия)**

2021



AQT90 FLEX
TECHNOPATH
Multi-CHECK COMBI
Level 1 (MCCI1)

REF 944-198 CONTROL 1 6 × 0.65 mL

LOT 06201 2022-06

Product of Ireland

Technopath Manufacturing Ltd
Fort Henry Business Park
Ballina
Co. Tipperary
Ireland
Tel: +353 61 525700



Distributed by

Radiometer Medical ApS
Akandevøj 21
2700 Brønshøj
Denmark



-20 °C
-80 °C



TECHNOPATH
CLINICAL DIAGNOSTICS

www.technopathcd.com

944-198 01

AQT90 FLEX
TECHNOPATH Multi-CHECK COMBI
Level 1 (MCCI1)



(01)05391523441605(17)220630(240)944-198(10)06201



TECHNOPATH
CLINICAL DIAGNOSTICS



TECHNOPATH Multi-CHECK Combi Level 1 & 2

	REF	CE	IVD
Level 1 Kit	944-198	CC911A	6 x 0.65 mL
Level 2 Kit	944-199	CC912A	6 x 0.65 mL

EN

INTENDED USE

For in vitro diagnostic use.
Multi-CHECK Combi is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the specifications insert.

PARAMETERS

C-Reactive Protein, D-Dimer, Human Cholesterol, Gonadotropin, Prolactin.

Contents:

Each tube contains 0.65 mL of control solution, enough for 5 tests.
This product is prepared from human serum to which purified biochemical material (cholesterol, human and animal serum, cholesterol, digoxigenin, and stabilizers have been added).

When stored correctly the unopened product is stable until the expiry date shown on the label.

Storage:

Shelf life:

Shelf life of the thawed product:

- The thawed product is stable for 2 hours (subambient, when tested at ambient temperature, maximum 30°C (86°F)).
- Analyses are stable for 4 days under these conditions with the exception of PCT (procalcitonin) which will be stable for 1 day when kept unthawed at 2-8°C (35-48°F).

NOTE: Do not refreeze.

Limitations of use:

- Product stability is dependent on its storage temperature, detailed specifications are provided for "Storage", "Shelf Life" and "Shelf Life of the thawed product". Do not use the product if it has not been kept according to these specifications, or if it has been damaged.
- If there is evidence of microbial contamination or exposure to heat in the product, discard the lot.

- This product is not intended for use as a standard or calibrator.
- Data in both inserts are the specifications insert contains:
 - Level name
 - Barcode type
 - Lot name
 - Area code
 - Empty site

Extra data in the barcode:

Upper and lower limits of the assigned control range.

Assigned value:

The assigned value is the center value of the assigned control range. The values are for specific. Values are provided as guidelines, each laboratory should establish its own statistical limits.

Quality control:

NOTE: LOC material must be regulated on the analyzer before use by using the barcode provided on the Specifications insert.

LOC measurements must be performed:

- after a calibration adjustment
- in accordance with local, national and/or international regulations or accreditation requirements.

See the AQT90 FLEX instructions for use document.

Preparation before use:

1. Remove the LOC solution from the freezer.
2. Let material thaw completely at ambient temperature of 15-25°C (59-77°F).
3. Analyze it within the time period specified in the "Shelf life of the thawed product" section above.

NOTE: Do not refreeze.

Handle and discard used LOC tubes as biohazardous waste. Failure to do so may result in exposure to potentially infected material. Dispose of all waste should be in accordance with local regulations. Material Safety

Warning:

Each human donor unit used to manufacture the LOC was tested using FDA-approved methods and found non-reactive for hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1.

HIV-2. This product may also contain other human source material for which there are no approved tests. In accordance with good laboratory practice, all human source materials should be considered potentially infectious and handled with the same precautions used with patient specimens.

BC

ПРЕДУПРЕЖДЕНИЕ

Защитно-дезинфекционные средства.
Материал, содержащий в себе биологический материал, может представлять опасность для здоровья при контакте с ним. Используйте защитные средства при работе с материалом. Соблюдайте все меры предосторожности.

ПОКАЗАТЕЛИ

Содержимое набора: Д-димер, холестерин, пролактин, пептиды, гормоны.
Содержимое набора: Д-димер, холестерин, пролактин, пептиды, гормоны.

Содержимое:

Каждый флакон содержит 0,65 мл раствора, достаточного для 5 тестов.

Срок годности:

Срок годности продукта при хранении в замороженном виде -20°C (или ниже) составляет 4 года.

Срок хранения:

После разморозки продукт можно использовать в течение 4 дней при температуре хранения +2°C.

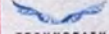
Срок годности:

После разморозки продукт можно использовать в течение 4 дней при температуре хранения +2°C.

TECHNOPATH



TECHNOPATH Multi-CHECK COMBI Level 1 (MCC11)



AQT90 FLEX
TECHNOPATH
Multi-CHECK COMBI
Level 1 (MCC11)

REF 944-198 CONTROL 1 6 x 0.65 mL

LOT 06201 2022-06

Product of origin: Technopath Manufacturing Ltd, Fort Henry Business Park, Belfast, Co. Tyrone, Ireland. Tel: +353 61 525706.

Distributed by: Mediatech Medical ApS, Asnavej 21, 2700 Brønshøj, Denmark.

-80 °C

20 °C

TECHNOPATH

CLINICAL DIAGNOSTICS

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AQT90 FLEX
TECHNOPATH
Multi-CHECK COMBI
Level 2 (MCCI2)



REF 944-199 CONTROL 2 6 × 0.65 mL



LOT 06202 2022-06



Product of Ireland:

Distributed by:

Technopath Manufacturing Ltd
Fort Henry Business Park
Ballina
Co. Tipperary
Ireland
Tel. +353 61 525700

Radiometer Medical ApS
Akandevøj 21
2700 Brønshøj
Denmark



-80 °C -20 °C



TECHNOPATH
CLINICAL DIAGNOSTICS

www.technopathcd.com

944-199-01

AQT90 FLEX
TECHNOPATH Multi-CHECK COMBI
Level 2 (MCCI2)



(01)05391523441599(17)220630(240)944-199(10)06202



TECHNOPATH
CLINICAL DIAGNOSTICS



TECHNOPATH Multi-CHECK Combi Level 1 & 2

	REF	CE	IVD
Level 1 Kit	944-198	CC911A	6 × 0.65 mL
Level 2 Kit	944-199	CC912A	6 × 0.65 mL

EN

INTENDED USE

For in vitro diagnostic use.
Multi-CHECK Combi is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the specifications insert.

PARAMETERS

C-Reactive Protein, D-Dimer, Human Chorionic Gonadotropin, Procalcitonin
Contents: 6 tubes with caps. • Specifications insert.
Components: Each tube contains 0.65 mL of control solution enough for 5 tests.
Composition: This product is prepared from human serum to which purified biochemical material (extracts of human and animal origin), chemical stabilizers, and preservatives have been added.
Storage: Store the unopened product at -20 °C (-4 °F) or colder.
Shelf life: When stored correctly the unopened product is stable until the expiry date shown on the label.

Shelf life of the thawed product: • The thawed product is stable for 2 hours (maximum), when kept unused at ambient temperature, maximum 30 °C (86 °F).
• Analytes are stable for 4 days under these conditions with the exception of PCT (Procalcitonin) which will be stable for 1 day when kept unused at 2-8 °C (36-68 °F).
NOTE: Do not refreeze.

Limitations of use:

• Product stability is dependent on its storage temperature, detailed specifications are provided for "Storage", "Shelf Life" and "Shelf life of the thawed product". Do not use the product if it has not been kept according to these specifications, or if it has been damaged.
• If there is evidence of microbial contamination or excessive turbidity in the product, discard the tube.
• This product is not intended for use as a standard or calibrator.
Data in both barcodes on the specifications insert contains:
• Checksum • Level name • Barcode type
• Lot no. • Area code • Expiry date
Extra data in the barcodes:
Upper and lower limits of the assigned control range
Assigned value

The assigned value is the center value of the assigned control range. The values are lot-specific. Values are provided as guidelines, each laboratory should establish its own statistical limits.
Quality control
NOTE: LQC material must be registered on the analyzer before use by using the barcodes provided on the Specifications insert.
LQC measurements must be performed:
• after a calibration adjustment
• in accordance with local, national and/or international regulations or accreditation requirements
See the AQT90 FLEX instructions for use document.

Preparation before use:
1. Remove the LQC solution from the freezer.
2. Let material thaw completely at ambient temperature of 15-25 °C (59-77 °F).
3. Analyze it within the time period specified in the "Shelf life of the thawed product" section above.

NOTE: Do not refreeze.
WARNING - Risk of Infection
Handle and discard used LQC tubes as biohazardous waste. Failure to do so may result in exposure to potentially infected material. Dispose of all waste should be in accordance with local regulations. Material Safety Data Sheet (MSDS) is available on request.

WARNING - Potentially Infectious material
Each human donor unit used to manufacture the LQC was tested using FDA-accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1.
HIV-2. This product may also contain other human source material for which there are no approved tests, in accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

! Data Sheet (MSDS) is available on request.

! WARNING - Potentially Infectious material
Each human donor unit used to manufacture the LQC was tested using FDA-accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1.

HIV-2. This product may also contain other human source material for which there are no approved tests, in accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

RU

ПРЕДНАЗНАЧЕНИЕ

Для in vitro диагностического использования.
Multi-CHECK Combi предназначен для использования как аналитический материал для мониторинга точности лабораторных тестов на показатели, указанные в спецификации.

ПОКАЗАТЕЛИ

C-реактивный белок, D-димер, бета-хорионический гонадотропин, прокальцитонин
Составление: 6 пробирок с крышками. • Спецификация в комплекте.
Компоненты: Каждая пробирка содержит 0,65 мл контрольного раствора.

Состав: Этот продукт был произведен из человеческого сыворотки, к которой были добавлены очищенные биохимические материалы (экстракты из человека и животного происхождения), стабилизаторы, консерванты и другие вещества.

Срок годности: Срок годности неопечатанного продукта при температуре -20 °C (-4 °F) или холоднее.
Срок годности размороженного, неиспользованного продукта: Стабилен до 2 часов при комнатной температуре.
• Размораживать продукт в течение до 2 часов (максимум).

IFU 067-115.01
01-2020

TECHNOPATH



AQT90 FLEX
TECHNOPATH
Multi-CHECK COMBI
Level 2 (MCC12)



AQT90 FLEX
TECHNOPATH
Multi-CHECK COMBI
Level 2 (MCC12)

REF 944-199 CONTROL 2 6 × 0.65 mL
LOT 06202 2022-06

Product of Ireland
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Distributed by:
Radcliffe Medical AG
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2700 Bremen
Germany

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Multi-CHECK Combi Level 2 (MCCI2)

REF CC912A

-80°C → -20°C

LOT 06202

Промито и стерилизовано
платино и вбгрисено
9 листов.
Генеральный директор
ООО "Радиометр"
Андрей Петрович С.Р.

