

For Professional Use Only
REF L006080101003 **IVD**
SPEC-35868 R1 ART-02674 R1 Date of Rev 2022-08

The LumiraDx HbA1c Quality Controls (hereafter referred to as Quality Controls) are optional quality controls to be used with the LumiraDx Instrument (hereafter referred to as the instrument) and the LumiraDx HbA1c Test (hereafter referred to as HbA1c Test).

Read these instructions thoroughly before using the Quality Controls. Inspect the Quality Controls packaging and contents for damage before use. Report any damage to LumiraDx Customer Services and do not use the kit if any damage is observed to the contents. The Quality Controls are intended for professional use only.

Intended Use: The LumiraDx HbA1c Quality Controls are intended for use by laboratory professionals/healthcare professionals to automated quality control testing performed on the LumiraDx Instrument when used with the LumiraDx HbA1c Test Strip. The Quality Controls provide users with assurance that the device is performing within specification.

To ensure that you are using the instrument, the specific assay test and the Quality Controls correctly, read the appropriate instrument User Manual, the specific assay test Product Manual and the entire Product insert. In addition, please watch the LumiraDx Platform Training video available at lumiraDx.com. The Quality Controls are intended for professional use only.

Summary and explanation of the test: The LumiraDx HbA1c Quality Controls are an optional quality control for the instrument when used with the LumiraDx HbA1c Test. The Quality Control material is used for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and may be used for proficiency testing. Quality Control testing policy is at the discretion of your organization and the frequency of testing will be determined by local guidelines.

Reagents: Each Quality Control kit contains human whole blood, stabilizers, and a specified level of glycated Hemoglobin (HbA1c). The Quality Control ranges are assigned by the LumiraDx HbA1c Test Strip. The LumiraDx HbA1c Test Strip performance is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) primary reference method for the measurement of HbA1c.

Warnings and precautions:
 For in vitro diagnostic use. For clinical contact human source material that was tested and found non-reactive for the Human Immunodeficiency Virus (HIV 1 and 2) antibody, Hepatitis B Surface Antigen (HbSag) and Hepatitis C antibody (anti-HCV). All detected or not with copious amounts of visible, seek immediate medical attention. Exercise the normal precautions required for handling of laboratory reagents.

All components of the kit can be discarded as biohazardous waste according to the local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information; the product safety data sheet is available at lumiraDx.com.

Storage and stability:
 Store controls between 2°C and 8°C (36–46°F). **DO NOT FREEZE.** Allow the Quality Controls material to come up to room temperature (15–30°C; 59–86°F) for at least 10 minutes (but not above that for 2 hours) before use.
 Unopened, controls that are stored between 2°C and 8°C (36–46°F) can be used until the expiration date.
 Controls are stable for 30 days between 2°C and 8°C (36–46°F) after opening.

Materials provided:
 • 3 x 0.5 mL vials Level 1 Quality Control stabilised whole blood
 • 3 x 0.5 mL vials Level 2 Quality Control stabilised whole blood
 • 40 x 20µL Single-Bub Plastic Transfer Pipettes (single use)
 • LumiraDx HbA1c Quality Control Pack Insert

Materials required but not provided with the Quality Control carton
 • LumiraDx Instrument
 • LumiraDx HbA1c Test Strips
 • LumiraDx Connect – if connectivity required (refer to LumiraDx Connect User Manual)
 • Quality Control Ranges Product Insert (included in the HbA1c Test Strip Carton)

Performance characteristics: Quality Control precision was determined in measurement system analysis for the Quality Controls with the LumiraDx HbA1c Test. The results were generated over multiple days, by multiple operators and instruments. The HbA1c results are shown in the following units of measurement:
 mmol/mol (IFCC)
 %HbA1c (NGSP)

Quality Control Level 1	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.7	0.33	5.8	845	

mmol/mol	39	3.42	8.7	845
----------	----	------	-----	-----

Quality Control Level 2	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	9.4	0.27	2.9	870	

mmol/mol	79	3.23	4.1	870
----------	----	------	-----	-----

Limitations: The product is designed as a Quality Control performed by the LumiraDx Platform for HbA1c. The Quality Control result is subjected to the limitations of the test Platform. Deviations may indicate potential problems with one or more components in the test Platform. The LumiraDx Instrument, LumiraDx Test Strips, how on-board controls to detect errors and internal base results when analysis is performed. Therefore, deviations observed when testing with the LumiraDx HbA1c Quality Controls would not invalidate previous results obtained from LumiraDx tests.

LumiraDx Customer Service: For product details contact LumiraDx Customer Services on 08000 58647239 or by email: customerservices@lumiraDx.com. Further information is available on www.lumiraDx.com. Any adverse results experienced with the use of this product and/or quality problems should also be reported to LumiraDx Customer Services using the above contact details.

Return policy: If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning product, please obtain a return authorization number from LumiraDx Customer Services. The return authorization number must be on the shipping cartons for return. For ordinary returns following purchase, please contact Customer Services for terms and conditions.

Limited warranty: LumiraDx Quality Controls – As per shelf life. For the applicable warranty period, LumiraDx warrants that each product shall be (a) of good quality and free of material defects, (b) function in accordance with the material specifications referenced in the pack insert, and (c) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty then as the customer's sole remedy LumiraDx shall repair or replace, at LumiraDx's discretion, the LumiraDx HbA1c Quality Controls (except for the limited warranty stated in this section. LumiraDx disclaims any and all warranties, express or implied, including but not limited to any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be

liable to the other party for any accidental or consequential damages, including without limitation loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result.

The Limited Warranty above shall not apply if the customer has subjected the LumiraDx Test Strips and Controls to physical abuse, misuse, abnormal use, use inconsistent with the LumiraDx Platform User Manual, LumiraDx Test Product Insert or HbA1c Quality Control Pack insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by Customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

FRANÇAIS
lumiraDx™ Contrôles qualité HbA1c

Réserveré à un usage professionnel
REF L006080101003 **IVD**
SPEC-35868 R1 ART-02674 R1 Date de révision 08-2022

The LumiraDx HbA1c Quality Controls (hereafter referred to as Quality Controls) are optional quality controls to be used with the LumiraDx Instrument (hereafter referred to as the instrument) and the LumiraDx HbA1c Test (hereafter referred to as HbA1c Test).

Read these instructions thoroughly before using the Quality Controls. Inspect the Quality Controls packaging and contents for damage before use. Report any damage to LumiraDx Customer Services and do not use the kit if any damage is observed to the contents. The Quality Controls are intended for professional use only.

To ensure that you are using the instrument, the specific assay test and the Quality Controls correctly, read the appropriate instrument User Manual, the specific assay test Product Manual and the entire Product insert. In addition, please watch the LumiraDx Platform Training video available at lumiraDx.com. The Quality Controls are intended for professional use only.

Summary and explanation of the test: The LumiraDx HbA1c Quality Controls are an optional quality control for the instrument when used with the LumiraDx HbA1c Test. The Quality Control material is used for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and may be used for proficiency testing. Quality Control testing policy is at the discretion of your organization and the frequency of testing will be determined by local guidelines.

Reagents: Each Quality Control kit contains human whole blood, stabilizers, and a specified level of glycated Hemoglobin (HbA1c). The Quality Control ranges are assigned by the LumiraDx HbA1c Test Strip. The LumiraDx HbA1c Test Strip performance is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) primary reference method for the measurement of HbA1c.

Warnings and precautions:
 For in vitro diagnostic use. For clinical contact human source material that was tested and found non-reactive for the Human Immunodeficiency Virus (HIV 1 and 2) antibody, Hepatitis B Surface Antigen (HbSag) and Hepatitis C antibody (anti-HCV). All detected or not with copious amounts of visible, seek immediate medical attention. Exercise the normal precautions required for handling of laboratory reagents.

All components of the kit can be discarded as biohazardous waste according to the local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information; the product safety data sheet is available at lumiraDx.com.

Storage and stability:
 Store controls between 2°C and 8°C (36–46°F). **DO NOT FREEZE.** Allow the Quality Controls material to come up to room temperature (15–30°C; 59–86°F) for at least 10 minutes (but not above that for 2 hours) before use.
 Unopened, controls that are stored between 2°C and 8°C (36–46°F) can be used until the expiration date.
 Controls are stable for 30 days between 2°C and 8°C (36–46°F) after opening.

Materials provided:
 • 3 x 0.5 mL vials Level 1 Quality Control stabilised whole blood
 • 3 x 0.5 mL vials Level 2 Quality Control stabilised whole blood
 • 40 x 20µL Single-Bub Plastic Transfer Pipettes (single use)
 • LumiraDx HbA1c Quality Control Pack Insert

Materials required but not provided with the Quality Control carton
 • LumiraDx Instrument
 • LumiraDx HbA1c Test Strips
 • LumiraDx Connect – if connectivity required (refer to LumiraDx Connect User Manual)
 • Quality Control Ranges Product Insert (included in the HbA1c Test Strip Carton)

Performance characteristics: Quality Control precision was determined in measurement system analysis for the Quality Controls with the LumiraDx HbA1c Test. The results were generated over multiple days, by multiple operators and instruments. The HbA1c results are shown in the following units of measurement:
 mmol/mol (IFCC)
 %HbA1c (NGSP)

Quality Control Level 1	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.7	0.33	5.8	845	

mmol/mol	39	3.42	8.7	845
----------	----	------	-----	-----

Quality Control Level 2	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	9.4	0.27	2.9	870	

mmol/mol	79	3.23	4.1	870
----------	----	------	-----	-----

Limitations: The product is designed as a Quality Control performed by the LumiraDx Platform for HbA1c. The Quality Control result is subjected to the limitations of the test Platform. Deviations may indicate potential problems with one or more components in the test Platform. The LumiraDx Instrument, LumiraDx Test Strips, how on-board controls to detect errors and internal base results when analysis is performed. Therefore, deviations observed when testing with the LumiraDx HbA1c Quality Controls would not invalidate previous results obtained from LumiraDx tests.

LumiraDx Customer Service: For product details contact LumiraDx Customer Services on 08000 58647239 or by email: customerservices@lumiraDx.com. Further information is available on www.lumiraDx.com. Any adverse results experienced with the use of this product and/or quality problems should also be reported to LumiraDx Customer Services using the above contact details.

Return policy: If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning product, please obtain a return authorization number from LumiraDx Customer Services. The return authorization number must be on the shipping cartons for return. For ordinary returns following purchase, please contact Customer Services for terms and conditions.

Limited warranty: LumiraDx Quality Controls – As per shelf life. For the applicable warranty period, LumiraDx warrants that each product shall be (a) of good quality and free of material defects, (b) function in accordance with the material specifications referenced in the pack insert, and (c) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty then as the customer's sole remedy LumiraDx shall repair or replace, at LumiraDx's discretion, the LumiraDx HbA1c Quality Controls (except for the limited warranty stated in this section. LumiraDx disclaims any and all warranties, express or implied, including but not limited to any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be

FRANÇAIS
lumiraDx™ Contrôles qualité HbA1c

Réserveré à un usage professionnel
REF L006080101003 **IVD**
SPEC-35868 R1 ART-02674 R1 Date de révision 08-2022

The LumiraDx HbA1c Quality Controls (hereafter referred to as Quality Controls) are optional quality controls to be used with the LumiraDx Instrument (hereafter referred to as the instrument) and the LumiraDx HbA1c Test (hereafter referred to as HbA1c Test).

Read these instructions thoroughly before using the Quality Controls. Inspect the Quality Controls packaging and contents for damage before use. Report any damage to LumiraDx Customer Services and do not use the kit if le contenu est visiblement endommagé.

To ensure that you are using the instrument, the specific assay test and the Quality Controls correctly, read the appropriate instrument User Manual, the specific assay test Product Manual and the entire Product insert. In addition, please watch the LumiraDx Platform Training video available at lumiraDx.com. The Quality Controls are intended for professional use only.

Summary and explanation of the test: The LumiraDx HbA1c Quality Controls are an optional quality control for the instrument when used with the LumiraDx HbA1c Test. The Quality Control material is used for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and may be used for proficiency testing. Quality Control testing policy is at the discretion of your organization and the frequency of testing will be determined by local guidelines.

Reagents: Each Quality Control kit contains human whole blood, stabilizers, and a specified level of glycated Hemoglobin (HbA1c). The Quality Control ranges are assigned by the LumiraDx HbA1c Test Strip. The LumiraDx HbA1c Test Strip performance is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) primary reference method for the measurement of HbA1c.

Warnings and precautions:
 For in vitro diagnostic use. For clinical contact human source material that was tested and found non-reactive for the Human Immunodeficiency Virus (HIV 1 and 2) antibody, Hepatitis B Surface Antigen (HbSag) and Hepatitis C antibody (anti-HCV). All detected or not with copious amounts of visible, seek immediate medical attention. Exercise the normal precautions required for handling of laboratory reagents.

All components of the kit can be discarded as biohazardous waste according to the local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information; the product safety data sheet is available at lumiraDx.com.

Storage and stability:
 Store controls between 2°C and 8°C (36–46°F). **DO NOT FREEZE.** Allow the Quality Controls material to come up to room temperature (15–30°C; 59–86°F) for at least 10 minutes (but not above that for 2 hours) before use.
 Unopened, controls that are stored between 2°C and 8°C (36–46°F) can be used until the expiration date.
 Controls are stable for 30 days between 2°C and 8°C (36–46°F) after opening.

Materials provided:
 • 3 x 0.5 mL vials Level 1 Quality Control stabilised whole blood
 • 3 x 0.5 mL vials Level 2 Quality Control stabilised whole blood
 • 40 x 20µL Single-Bub Plastic Transfer Pipettes (single use)
 • LumiraDx HbA1c Quality Control Pack Insert

Materials required but not provided with the Quality Control carton
 • LumiraDx Instrument
 • LumiraDx HbA1c Test Strips
 • LumiraDx Connect – if connectivity required (refer to LumiraDx Connect User Manual)
 • Quality Control Ranges Product Insert (included in the HbA1c Test Strip Carton)

Performance characteristics: Quality Control precision was determined in measurement system analysis for the Quality Controls with the LumiraDx HbA1c Test. The results were generated over multiple days, by multiple operators and instruments. The HbA1c results are shown in the following units of measurement:
 mmol/mol (IFCC)
 %HbA1c (NGSP)

Quality Control Level 1	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.7	0.33	5.8	845	

mmol/mol	39	3.42	8.7	845
----------	----	------	-----	-----

Quality Control Level 2	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	9.4	0.27	2.9	870	

mmol/mol	79	3.23	4.1	870
----------	----	------	-----	-----

Limitations: The product is designed as a Quality Control performed by the LumiraDx Platform for HbA1c. The Quality Control result is subjected to the limitations of the test Platform. Deviations may indicate potential problems with one or more components in the test Platform. The LumiraDx Instrument, LumiraDx Test Strips, how on-board controls to detect errors and internal base results when analysis is performed. Therefore, deviations observed when testing with the LumiraDx HbA1c Quality Controls would not invalidate previous results obtained from LumiraDx tests.

LumiraDx Customer Service: For product details contact LumiraDx Customer Services on 08000 58647239 or by email: customerservices@lumiraDx.com. Further information is available on www.lumiraDx.com. Any adverse results experienced with the use of this product and/or quality problems should also be reported to LumiraDx Customer Services using the above contact details.

Return policy: If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning product, please obtain a return authorization number from LumiraDx Customer Services. The return authorization number must be on the shipping cartons for return. For ordinary returns following purchase, please contact Customer Services for terms and conditions.

Limited warranty: LumiraDx Quality Controls – As per shelf life. For the applicable warranty period, LumiraDx warrants that each product shall be (a) of good quality and free of material defects, (b) function in accordance with the material specifications referenced in the pack insert, and (c) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty then as the customer's sole remedy LumiraDx shall repair or replace, at LumiraDx's discretion, the LumiraDx HbA1c Quality Controls (except for the limited warranty stated in this section. LumiraDx disclaims any and all warranties, express or implied, including but not limited to any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be

FRANÇAIS
lumiraDx™ Contrôles qualité HbA1c

Réserveré à un usage professionnel
REF L006080101003 **IVD**
SPEC-35868 R1 ART-02674 R1 Date de révision 08-2022

The LumiraDx HbA1c Quality Controls (hereafter referred to as Quality Controls) are optional quality controls to be used with the LumiraDx Instrument (hereafter referred to as the instrument) and the LumiraDx HbA1c Test (hereafter referred to as HbA1c Test).

Read these instructions thoroughly before using the Quality Controls. Inspect the Quality Controls packaging and contents for damage before use. Report any damage to LumiraDx Customer Services and do not use the kit if le contenu est visiblement endommagé.

To ensure that you are using the instrument, the specific assay test and the Quality Controls correctly, read the appropriate instrument User Manual, the specific assay test Product Manual and the entire Product insert. In addition, please watch the LumiraDx Platform Training video available at lumiraDx.com. The Quality Controls are intended for professional use only.

Summary and explanation of the test: The LumiraDx HbA1c Quality Controls are an optional quality control for the instrument when used with the LumiraDx HbA1c Test. The Quality Control material is used for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and may be used for proficiency testing. Quality Control testing policy is at the discretion of your organization and the frequency of testing will be determined by local guidelines.

Reagents: Each Quality Control kit contains human whole blood, stabilizers, and a specified level of glycated Hemoglobin (HbA1c). The Quality Control ranges are assigned by the LumiraDx HbA1c Test Strip. The LumiraDx HbA1c Test Strip performance is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) primary reference method for the measurement of HbA1c.

Warnings and precautions:
 For in vitro diagnostic use. For clinical contact human source material that was tested and found non-reactive for the Human Immunodeficiency Virus (HIV 1 and 2) antibody, Hepatitis B Surface Antigen (HbSag) and Hepatitis C antibody (anti-HCV). All detected or not with copious amounts of visible, seek immediate medical attention. Exercise the normal precautions required for handling of laboratory reagents.

All components of the kit can be discarded as biohazardous waste according to the local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information; the product safety data sheet is available at lumiraDx.com.

Storage and stability:
 Store controls between 2°C and 8°C (36–46°F). **DO NOT FREEZE.** Allow the Quality Controls material to come up to room temperature (15–30°C; 59–86°F) for at least 10 minutes (but not above that for 2 hours) before use.
 Unopened, controls that are stored between 2°C and 8°C (36–46°F) can be used until the expiration date.
 Controls are stable for 30 days between 2°C and 8°C (36–46°F) after opening.

Materials provided:
 • 3 x 0.5 mL vials Level 1 Quality Control stabilised whole blood
 • 3 x 0.5 mL vials Level 2 Quality Control stabilised whole blood
 • 40 x 20µL Single-Bub Plastic Transfer Pipettes (single use)
 • LumiraDx HbA1c Quality Control Pack Insert

Materials required but not provided with the Quality Control carton
 • LumiraDx Instrument
 • LumiraDx HbA1c Test Strips
 • LumiraDx Connect – if connectivity required (refer to LumiraDx Connect User Manual)
 • Quality Control Ranges Product Insert (included in the HbA1c Test Strip Carton)

Performance characteristics: Quality Control precision was determined in measurement system analysis for the Quality Controls with the LumiraDx HbA1c Test. The results were generated over multiple days, by multiple operators and instruments. The HbA1c results are shown in the following units of measurement:
 mmol/mol (IFCC)
 %HbA1c (NGSP)

Quality Control Level 1	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.7	0.33	5.8	845	

mmol/mol	39	3.42	8.7	845
----------	----	------	-----	-----

Quality Control Level 2	Unit of Measurement	Mean	SD	%CV	N
%HbA1c	9.4	0.27	2.9	870	

mmol/mol	79	3.23	4.1	870
----------	----	------	-----	-----

Limitations: The product is designed as a Quality Control performed by the LumiraDx Platform for HbA1c. The Quality Control result is subjected to the limitations of the test Platform. Deviations may indicate potential problems with one or more components in the test Platform. The LumiraDx Instrument, LumiraDx Test Strips, how on-board controls to detect errors and internal base results when analysis is performed. Therefore, deviations observed when testing with the LumiraDx HbA1c Quality Controls would not invalidate previous results obtained from LumiraDx tests.

LumiraDx Customer Service: For product details contact LumiraDx Customer Services on 08000 58647239 or by email: customerservices@lumiraDx.com. Further information is available on www.lumiraDx.com. Any adverse results experienced with the use of this product and/or quality problems should also be reported to LumiraDx Customer Services using the above contact details.

Return policy: If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning product, please obtain a return authorization number from LumiraDx Customer Services. The return authorization number must be on the shipping cartons for return. For ordinary returns following purchase, please contact Customer Services for terms and conditions.

Limited warranty: LumiraDx Quality Controls – As per shelf life. For the applicable warranty period, LumiraDx warrants that each product shall be (a) of good quality and free of material defects, (b) function in accordance with the material specifications referenced in the pack insert, and (c) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty then as the customer's sole remedy LumiraDx shall repair or replace, at LumiraDx's discretion, the LumiraDx HbA1c Quality Controls (except for the limited warranty stated in this section. LumiraDx disclaims any and all warranties, express or implied, including but not limited to any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be

Procédure/réalisation d'un test : Consulter le manuel d'utilisation de la Platorm LumiraDx pour des instructions sur comment analyser un échantillon de Contrôle qualité. Ouvrir le sachet en aluminium de la Carte Microfluidique HbA1c juste avant son utilisation et insérer la Carte Microfluidique dans l'instrument LumiraDx. L'instrument indiquera quand l'échantillon peut être appliqué.

Utiliser la Carte Microfluidique immédiatement après l'avoir retirée du sachet en aluminium. Ne pas utiliser la Carte Microfluidique si il y a des signes visibles d'endommagement ou si le sachet en aluminium, mais que des déchirures ou des trous.

Lors du transfert de la solution de Contrôle qualité sur la Carte Microfluidique à partir du flacon, une pipette de transfert (ou équivalente, capable de capter avec précision 20 µL de solution de Contrôle qualité) peut être utilisée. Les Contrôles qualité HbA1c LumiraDx ne doivent pas être appliqués dans une zone d'application de l'échantillon de la Carte Microfluidique. Acceptable étape de tampon de lise si est requis pour réaliser un test de contrôle qualité HbA1c LumiraDx.

Les Contrôles qualité HbA1c LumiraDx (ci-après appelés : Contrôles qualité) et sont des contrôles qualité facultatifs à utiliser avec l'instrument LumiraDx (ci-après appelé : l'instrument) et le test HbA1c LumiraDx (ci-après appelé : test HbA1c Test).

Intended Use: The LumiraDx HbA1c Quality Controls are intended for use by laboratory professionals/healthcare professionals to automated quality control testing performed on the LumiraDx Instrument when used with the LumiraDx HbA1c Test Strip. The Quality Controls provide users with assurance that the device is performing within specification.

To ensure that you are using the instrument, the specific assay test and the Quality Controls correctly, read the appropriate instrument User Manual, the specific assay test Product Manual and the entire Product insert. In addition, please watch the LumiraDx Platform Training video available at lumiraDx.com. The Quality Controls are intended for professional use only.

Summary and explanation of the test: The LumiraDx HbA1c Quality Controls are an optional quality control for the instrument when used with the LumiraDx HbA1c Test. The Quality Control material is used for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and may be used for proficiency testing. Quality Control testing policy is at the discretion of your organization and the frequency of testing will be determined by local guidelines.

Reagents: Each Quality Control kit contains human whole blood, stabilizers, and a specified level of glycated Hemoglobin (HbA1c). The Quality Control ranges are assigned by the LumiraDx HbA1c Test Strip. The LumiraDx HbA1c Test Strip performance is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) primary reference method for the measurement of HbA1c.

Warnings and precautions:
 For

lumiraDx™ Controlli di Qualità HbA1c

Solo per uso professionale

REF L0608010103 IVD

SPEC-35868 R1

ART-02674 R1 Data di revisione 2022/08

I Controlli di Qualità LumiraDx HbA1c (è seguito dal nome "Controllo di Qualità") sono controllati di qualità opzionali da utilizzare con il LumiraDx Instrument (il sigello indicato come "Instrument") e il Test LumiraDx HbA1c (è seguito indicato come "test HbA1c").

Leggere attentamente le presenti istruzioni prima di utilizzare i Controlli di Qualità.

Prima dell'uso, esaminare la confezione e il contenuto del Controllo di Qualità per escludere la presenza di danni. Segnare qualsiasi eventuale danno all'assistenza clienti LumiraDx e non usare il kit qualora si rilevi un qualsiasi danno al contenuto.

I Controlli di Qualità sono destinati esclusivamente all'uso professionale.

Uso previsto

I Controlli di Qualità LumiraDx HbA1c sono previsti per l'uso da parte di operatori di laboratorio/operatori sanitari per test di controllo di qualità automatizzati eseguiti su LumiraDx Instrument utilizzati con la Strisce Reattive LumiraDx HbA1c. I Controlli di Qualità offrono agli operatori la certezza che le prestazioni del dispositivo rientrano nelle specifiche.

Per essere certi di utilizzare correttamente l'Instrument il test con dosaggio specifico e i Controlli di Qualità, leggere il Manuale d'uso della Piattaforma appropriata, il foglietto illustrativo del test dosaggio specifico e il presente foglietto illustrativo. Inoltre, guardare il video di formazione per LumiraDx Platform disponibile su lumiradx.com. I Controlli di Qualità sono destinati esclusivamente all'uso professionale.

Controlli e spiegazione del test

I Controlli di Qualità LumiraDx HbA1c sono controlli di qualità opzionali per l'Instrument, se utilizzato con il Test LumiraDx HbA1c. Il materiale di Controllo di Qualità è previsto per scopi clinici per essere utilizzato in un sistema analitico per rilevare la precisione e rilevare deviazioni sistematiche che possono essere causate dal reagente o da variazioni del sistema analitico. Tale materiale può essere usato per le prove interlaboratorie. Il nome sui test di controllo di qualità sono a discrezione dell'organizzazione e la frequenza dei test sarà determinata dalle linee guida locali.

Reagenti

Ciascun kit di Controllo di Qualità contiene sangue intero umano stabilizzato in un livello specifico di emoglobina glicosilata (HbA1c). Gli intervalli del Controllo di Qualità sono assegnati dagli Specifici Reattivi LumiraDx HbA1c. Le prestazioni delle Strisce Reattive LumiraDx HbA1c sono prestazioni generali secondo l'International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), principale metodo di riferimento per la misurazione di HbA1c.

Avvertenze e precauzioni

- Per uso diagnostico in vitro
- Questo controllo contiene materiale di origine umana analizzato e risultato non reattivo agli anticorpi anti-HIV-1 e 2, anti-sifilide, anti-hepatite A, B e C, anti-sifilide e anti-hepatite C.
- Questo controllo contiene il virus dell'epatite C (antiHCV) allo stadio di donatore. Questo prodotto è progettato per il controllo di qualità e non deve essere usato per scopi diagnostici. Questo controllo non deve essere utilizzato per scopi diagnostici. Questo controllo può contenere virus della sifilide e altri agenti antiparassitari e stabilizzanti. Evitare l'ingestione o il contatto con pelle e mucose. In caso di contatto con la pelle, sciacquare l'area colpita con abbondante acqua. Se si manifesta una reazione cutanea, rivolgervi a un medico. In caso di contatto con gli occhi di ingestione, schiacciare, assistere medico immediatamente.
- Adottare le normali precauzioni richieste per la manipolazione di tutti i reagenti di laboratorio.
- Tutti i componenti di questo kit possono essere smaltiti come rifiuti a rischio biologico nel rispetto delle linee guida locali.
- Consultare la scheda di sicurezza del prodotto per le test di controllo di qualità e le informazioni per lo smaltimento. La scheda di sicurezza del prodotto è disponibile sul sito lumiradx.com.
- Nel programma di controllo di qualità del centro è necessario integrare i requisiti dell'organismo di accreditamento o di certificazione competente.

Conservazione e stabilità

Conservare i controlli tra 2 °C e 8 °C (36 -46 °F). **NON CONGELARE.**

- Lasciare che il materiale di Controllo di Qualità si stabilizzi alla temperatura ambiente (15-30 °C / 59 -86 °F) per almeno 10 minuti (ma non oltre i 21 ore) prima dell'uso.
- I controlli in non aperti conservati tra 2 °C e 8 °C (36 -46 °F) possono essere usati fino alla data di scadenza.
- Dopo l'apertura, i controlli sono stabili per 30 giorni tra 2 °C e 8 °C (36 -46 °F).

Materiale fornito

- 3 x 0,5 mL, fiale di sangue intero stabilizzato con Controllo di Qualità livello 1
- 3 x 0,5 mL, fiale di sangue intero stabilizzato con Controllo di Qualità livello 2
- 40 x 20 µL pipette di trasferimento a bulbo singolo in plastica (monouso)
- Foglietto illustrativo dei Controlli di Qualità LumiraDx HbA1c

Materiale necessario ma non fornito nella confezione del Controllo di Qualità

- LumiraDx Instrument
- Strisce Reattive LumiraDx HbA1c
- LumiraDx Connect - se è richiesta la connettività (consultare il manuale d'uso di LumiraDx Connect)
- Foglietto illustrativo dei Controlli di Qualità LumiraDx HbA1c (incluso nella scatola delle Strisce Reattive HbA1c)

Preparazione del test

Saranno necessari i LumiraDx Instrument e il seguente materiale:

- Striscia (reattiva) LumiraDx HbA1c
- Controllo di Qualità LumiraDx HbA1c livello 1 o livello 2
- Pipette di trasferimento a bulbo singolo in plastica (monouso)

Preparazione dei Controlli di Qualità

I Controlli di Qualità liquidi sono forniti pronti all'uso.

Manipolazione delle Strisce Reattive LumiraDx HbA1c

Per essere certi di utilizzare correttamente il test HbA1c e il Platform, leggere il foglietto illustrativo della Striscia Reattiva HbA1c appropriata e il Manuale d'uso della Piattaforma.

Procedura/esecuzione di un test

Consultare il Manuale d'uso della LumiraDx Platform per istruzioni su come analizzare un campione di Controllo di Qualità. Aprire la busta in alluminio della Striscia Reattiva HbA1c immediatamente prima dell'uso e inserire la striscia nel LumiraDx Instrument. Il risultato è indicato quando è pronto per l'applicazione del campione.

Una volta rimossa dalla busta in alluminio, la Striscia Reattiva deve essere utilizzata immediatamente. Non usare la Striscia Reattiva in presenza di segni visibili di danneggiamento della busta in alluminio, come strappi o lacerazioni.

Durante il trasferimento della soluzione di Controllo di Qualità dalla fiala alla Striscia Reattiva, utilizzare una pipetta di trasferimento (o equivalente in grado di dispensare accuratamente 20 µL di soluzione di Controllo di Qualità) con l'etichetta di Qualità direttamente utilizzata in questa sezione. LumiraDx esclude qualsiasi altra garanzia, espresse o implicite, in compenso, in via esemplificativa ma non esaustiva, qualsiasi garanzia di commerciabilità, idoneità o scopi particolari o non esistenza riguardante il prodotto.

La responsabilità massima di LumiraDx per qualsiasi rivendicazione da parte del cliente non potrà superare il prezzo netto del prodotto pagato dal medesimo. Nessuno delle parti potrà essere ritenuta responsabile verso la controparte per danni speciali, eccezionali o consequenziali, inclusi, senza limitazioni, penali di affari, punitivi, dotti o risarc, anche nel caso in cui la parte interessata fosse previamente informata della possibilità di un tale danno.

La garanzia limitata di cui sopra non si applica in caso di uso delle Strisce Reattive e dei Controlli LumiraDx da parte del cliente in modo errato, improprio, anomalo o non conforme con le indicazioni fornite nel Manuale d'uso della LumiraDx Platform, nel foglietto illustrativo del LumiraDx Test o nel foglietto illustrativo del Controllo di Qualità HbA1c, come anche il seguir di frode, non autorizzate, collezioni, falsifiche, insulti, negligenza o incidenti. Qualsiasi richiesta di risarcimento da parte del cliente ai sensi della garanzia limitata dovrà essere presentata per iscritto entro il periodo di validità della garanzia limitata.

Controlli di Qualità LumiraDx

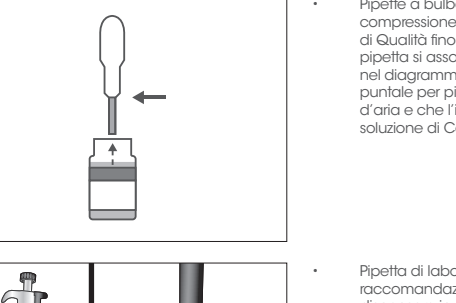
La garanzia limitata di cui sopra non si applica in caso di uso delle Strisce Reattive e dei Controlli LumiraDx da parte del cliente in modo errato, improprio, anomalo o non conforme con le indicazioni fornite nel Manuale d'uso della LumiraDx Platform, nel foglietto illustrativo del LumiraDx Test o nel foglietto illustrativo del Controllo di Qualità HbA1c, come anche il seguir di frode, non autorizzate, collezioni, falsifiche, insulti, negligenza o incidenti. Qualsiasi richiesta di risarcimento da parte del cliente ai sensi della garanzia limitata dovrà essere presentata per iscritto entro il periodo di validità della garanzia limitata.

Senza presente che le seguenti pipette di trasferimento sono accettate per l'uso con la soluzione di Controllo di Qualità LumiraDx HbA1c:

- Pipette di trasferimento a bulbo singolo in plastica da 20 µL (monouso)
- Pipetta di laboratorio calibrata (pipetta a 20 µL, con punte appropriate)

Tenere presente che le pipette di trasferimento utilizzate con i Controlli di Qualità LumiraDx HbA1c non devono mai contenere fumi, additivi, tensioattivi o conservanti.

- Aprire una fiala di Controllo di Qualità facendo molta attenzione a rimuovere il tappo in gomma.
- Aspire 20 µL della soluzione di Controllo di Qualità dalla fiala e trasferire in una pipetta con uno dei metodi seguenti:



Controlli di Qualità LumiraDx. In questa quarta di conservazione.

Per il periodo di validità della garanzia, LumiraDx garantisce che tutti i prodotti saranno (i) di buona qualità ed essere da difetti nei materiali, (ii) funzionanti in conformità con le specifiche dei materiali riportate nel foglietto illustrativo del pack e (iii) approvati per l'uso previsto dalle agenzie statali competenti per la vendita dei prodotti (la "garanzia limitata"). Qualora il prodotto non soddisfacesse i requisiti della garanzia limitata come unico rimedio a favore del cliente, LumiraDx riparerà o sostituirà, a propria discrezione, i Controlli di Qualità LumiraDx HbA1c. Fatta eccezione per la garanzia limitata riportata in questa sezione, LumiraDx esclude qualsiasi altra garanzia, espresse o implicite, in compenso, in via esemplificativa ma non esaustiva, qualsiasi garanzia di commerciabilità, idoneità o scopi particolari o non esistenza riguardante il prodotto.

La responsabilità massima di LumiraDx per qualsiasi rivendicazione da parte del cliente non potrà superare il prezzo netto del prodotto pagato dal medesimo. Nessuno delle parti potrà essere ritenuta responsabile verso la controparte per danni speciali, eccezionali o consequenziali, inclusi, senza limitazioni, penali di affari, punitivi, dotti o risarc, anche nel caso in cui la parte interessata fosse previamente informata della possibilità di un tale danno.

La garanzia limitata di cui sopra non si applica in caso di uso delle Strisce Reattive e dei Controlli LumiraDx da parte del cliente in modo errato, improprio, anomalo o non conforme con le indicazioni fornite nel Manuale d'uso della LumiraDx Platform, nel foglietto illustrativo del LumiraDx Test o nel foglietto illustrativo del Controllo di Qualità HbA1c, come anche il seguir di frode, non autorizzate, collezioni, falsifiche, insulti, negligenza o incidenti. Qualsiasi richiesta di risarcimento da parte del cliente ai sensi della garanzia limitata dovrà essere presentata per iscritto entro il periodo di validità della garanzia limitata.

Simbolo	Significato
	Limite di temperatura
	Fabbricante
	Importatore
	Distributore
	Dispositivo medico diagnostico in vitro
	Codice prodotto
	Numero di lotto
	Data "Usare entro" - indica la data dopo la quale l'IVD/materiale di Controllo di Qualità non aperto non può più essere utilizzato
	"Marchio CE" - Questo prodotto soddisfa i requisiti della Direttiva europea 98/79/CE sui dispositivi medico-diagnostici in vitro.
	Conformità del Regno Unito valutata ai sensi dei Medical Devices Regulations 2002 (SI 2002 n. 618 in versione modificata) (UK MDR 2002)
	Indica un materiale di controllo previsto per verificare le caratteristiche prestazionali del LumiraDx Instrument.
	Indica che il materiale di Controllo di Qualità sono associati potenziali rischi biologici.
	Consultate le istruzioni per l'uso
	Mandatario nell'Unione Europea

Simbolo	Significato
	Limite di temperatura
	Fabbricante
	Importatore
	Distributore
	Dispositivo medico diagnostico in vitro
	Codice prodotto
	Numero di lotto
	Data "Usare entro" - indica la data dopo la quale l'IVD/materiale di Controllo di Qualità non aperto non può più essere utilizzato
	"Marchio CE" - Questo prodotto soddisfa i requisiti della Direttiva europea 98/79/CE sui dispositivi medico-diagnostici in vitro.
	Conformità del Regno Unito valutata ai sensi dei Medical Devices Regulations 2002 (SI 2002 n. 618 in versione modificata) (UK MDR 2002)
	Indica un materiale di controllo previsto per verificare le caratteristiche prestazionali del LumiraDx Instrument.
	Indica che il materiale di Controllo di Qualità sono associati potenziali rischi biologici.
	Consultate le istruzioni per l'uso
	Mandatario nell'Unione Europea

- Applicare immediatamente la soluzione di Controllo di Qualità sulla Striscia Reattiva già inserita:** Inserire la pipetta sul foro di applicazione del campione della Striscia Reattiva e dispensare un'unica goccia di grandi dimensioni (20 µL) di soluzione di Controllo di Qualità nell'area di applicazione della Striscia Reattiva. In seguito, il campione verrà aspirato nella Striscia Reattiva per essere capillare. Quando rileva il campione, l'Instrument emetterà un segnale acustico (pulselli) suono sono udibili) e visualizzerà un messaggio di controllo. Gettare via la pipetta nell'apposito contenitore per i rifiuti clinici. Aspirare il risultato e il risultato è previsto in 60 secondi.
- Non aprire lo sportello mentre il test è in corso.** Il touchscreen indicherà l'avanzamento del test.
- Il risultato sarà visualizzato sui touchscreens dell'Instrument entro circa 7 minuti** dall'applicazione del campione e dall'ovvio del test. I risultati saranno visualizzati sullo schermo dell'Instrument come valore del test, intervallo accettabile, PASS (SUCCESSO) o FAIL (NON SUCCESSO).
- Gettare** la Striscia Reattiva e la pipetta di trasferimento (o il punto per pipetta di laboratorio) nell'apposito contenitore per i rifiuti clinici.
- NOTA:** Se occorre ripetere i test di Controllo di Qualità, utilizzare una nuova Striscia Reattiva e una pipetta di trasferimento/pipette per pipetta.

Risultati previsti

L'Instrument visualizza il valore del test, l'intervallo accettabile e il superamento o meno del test. È possibile consultare anche il foglietto illustrativo con gli intervalli di controllo contenuti nel foglietto illustrativo della Striscia Reattiva HbA1c per confermare che il risultato rientra nell'intervallo accettabile. Il risultato viene salvato automaticamente nella memoria dell'Instrument. Se i risultati dei test ottenuti rientrano nell'intervallo di controllo accettabile, come riportato nel foglietto illustrativo con gli intervalli del Controllo di Qualità, significa che il sistema sta funzionando correttamente e che tutte le operazioni sono state eseguite correttamente.

Informative legale

Copyright © 2022 LumiraDx UK e affiliaze. Tutti i diritti riservati. LumiraDx e il logo con la firma sono marchi protetti di LumiraDx International Ltd. Tutti i dettagli di questo e altri regolamenti di LumiraDx sono disponibili sul sito lumiradx.com. Tutti gli altri marchi di fabbrica sono di proprietà dei rispettivi titolari.

Informazioni sui fabbricanti

LumiraDx UK Ltd
LumiraDx House, Park, Alcock, FK10 2PB, Regno Unito.
Numero di registrazione: 09206123

EC REP LumiraDx AB, Västra Vögen 5A, 16961 Södra, Svezia

CE Il marchio CE si applica soltanto ai Controlli di Qualità Instrument, alle Strisce Reattive LumiraDx HbA1c e ai Connect Hub.

SPEC-35868 R1 ART-02674 R1 Data di revisione 2022/08

ESPAÑOL

lumiraDx™ Controles de calidad HbA1c

Solo para uso profesional

REF L0608010103 IVD

SPEC-35868 R1

ART-02674 R1 Fecha de revisión 08/2022

Los Controles de Calidad LumiraDx HbA1c (en adelante, Control de Calidad) son controles de calidad opcionales que se utilizan con el LumiraDx Instrument (en adelante, el Instrument) y el Test HbA1c (en adelante, el Test HbA1c).

Leas estas instrucciones en su totalidad antes de utilizar los Controles de Calidad.

Inspeccione de Verpackung in en Inhalt von de Qualität Kontrollen vor dem Gebrauch auf Beschädigung. Meld eventuelle schade an de Kundendienst von LumiraDx en gebrauch de kit mit des schade wort waargenomen aan de inhoud.

De Quality Controls zijn uitsluitend bestemd voor professioneel gebruik.

Beoogde gebruik

De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.

De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.

Overzicht van en toelichting op de test

De LumiraDx HbA1c Quality Controls zijn een optionele quality control voor het Instrument bij gebruik met de LumiraDx HbA1c Test. De Quality Control-toestellen is bestemd voor medische doeleinden, voor gebruik in een laboratorium, om de betrouwbaarheid te schakelen en systematische afwijkingen in de detectie te kunnen ontlasten als gevolg van variatie van magnitude of analytische instrumenten en kan worden gebruikt voor laboratoriumtoelating. Het Quality Control-toestel wordt bevestigd door uw organisatie en de testfrequentie wordt bepaald door plaatselijke richtlijn.

Reagentia:

Elas Quality Control bevat menselijk volbloed, stabilisator en een gespecificeerd niveau van glycosylende hemoglobine (HbA1c). De Quality Control-toestellen worden beregenen door de LumiraDx HbA1c Test. De gestalte van de LumiraDx HbA1c Testtip zijn individueel geïdentificeerd met een referentiemerkende voor de meting van HbA1c van de internationale federatie voor klinische chemie en laboratoriumgeneeskunde (International Federation of Clinical Chemistry and Laboratory Medicine, IFCC).

Waarschuwungen en voorzorgsmaatregelen:

- Voor gebruik bij in-vitro diagnose
- Deze controle bevat materiaal van menselijke oorsprong dat is gelijst en niet-toegankelijk te worden voor antilichamen tegen het immuunresponsysteem (EIV 1 en 2), hepatitis B-antipartikel-antigeen (HbAg) en hepatitis-C-virus (antiHCV) in het donorschuld.Dit product moet, in een laboratorium, om de betrouwbaarheid te schakelen en systematische afwijkingen in de detectie te kunnen ontlasten als gevolg van variatie van magnitude of analytische instrumenten en kan worden gebruikt voor laboratoriumtoelating. Het Quality Control-toestel wordt bevestigd door uw organisatie en de testfrequentie wordt bepaald door plaatselijke richtlijn.
- De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.
- Pas de normale voorzorgsmaatregelen toe die vereist zijn voor het hanteren van alle laboratoriumreagentia.
- Alle onderdelen van deze kit kunnen worden afgeworpen als biologisch gevaarlijk afval volgens de lokale richtlijn.
- Ze het veiligheidsinformatieblad bij het product voor risico- en veiligheidsinformatie en informatie over de oever. Het veiligheidsinformatieblad bij het product is verkrijgbaar op lumiradx.com.
- De eisen van de lokale bevoegde vergunning- of accreditatie-entiteit moeten worden gatgelegd in de quality controlprogramma.

Oplag en stabiliteit:

- De controle is op bij een temperatuur tussen 2 °C en 8 °C (36 °F-46 °F). **NIEF INVRIJZEN.**
- Laat het LumiraDx Instrument op kamertemperatuur komen (15 °C - 30 °C / 59 °F - 86 °F) gedurende tenminste 10 minuten (maar niet langer dan twee (2) uur) voorafgaand aan het gebruik.
- Ongedrukt controle die worden opgeslagen tussen 2 °C en 8 °C (36 °F-46 °F) worden gebruikt tot de uitvervaldatum.
- Controles zijn in opening 30 dagen lang stabiel tussen 2 °C en 8 °C (36 °F-46 °F).

Geleverde materialen:

- 3 x 0,5 mL flocans met gestabiliseerd volbloed voor Quality Control niveau 1
- 3 x 0,5 mL flocans met gestabiliseerd volbloed voor Quality Control niveau 2
- 40 x 20 µL, plastic overbrengingspipetten met één bol (voor eenmalig gebruik)
- 40 x 20 µL, plastic overbrengingspipetten met één bol (voor eenmalig gebruik)

Versteite benodigdheden die niet in de Quality Control-doos zijn ingeprengd

- LumiraDx Instrument
- LumiraDx HbA1c Teststrips
- LumiraDx Connect - als connectiviteit vereist is (zie de gebruikershandleiding van LumiraDx Connect)
- Bijlifter met Quality Control-toestellen (in de doos met HbA1c Teststrips)

Gereedmaken voor het testen:

U hebt het LumiraDx Instrument nodig evenals de volgende benodigdheden:

- Tias Reactives LumiraDx HbA1c
- Controles de Calidad LumiraDx HbA1c Niveau 1 o Nivel 2
- Pipetas de transferencia de plástico de una ampolla de 20 µL (de un solo uso)

Preparación de los Controles de Calidad:

Los Controles de Calidad líquidos se suministran listos para su uso.

Manipulación de las Tiras Reactivas LumiraDx HbA1c:

Para estar seguros de utilizar correctamente el test HbA1c e el Instrument, leo el prospecto de la Tira Reactiva HbA1c correspondiente e el manual del usuario de la Piattaform.

Controles de Calidad Nivel 1

Unidad de medida	Media	DE	% CV	N
% HbA1c	5,7	0,33	5,8	845

Preparación para el test:

Utilice el LumiraDx Instrument y los componentes siguientes:

- Tiras Reactivas LumiraDx HbA1c
- Controles de Calidad LumiraDx HbA1c Nivel 1 o Nivel 2
- Pipetas de transferencia de plástico de una ampolla (de un solo uso)

Preparación de los Controles de Calidad:

Los Controles de Calidad líquidos se suministran listos para su uso.

Control de Calidad Nivel 2

Unidad de medida	Media	DE	% CV	N
% HbA1c	9,4	0,27	2,9	870

Limitaciones:

Este producto está diseñado como un Control de Calidad realizado en la LumiraDx Platform para HbA1c. El resultado del Control de Calidad está sujeto a las limitaciones de la Piattaform de medición. Las desviaciones pueden indicar posibles problemas con uno o más componentes de la Piattaform de análisis. El LumiraDx Instrument y las Tiras Reactivas LumiraDx HbA1c tienen características integradas para detectar errores y evitar resultados falsos cuando se realiza el análisis. Por lo tanto, las desviaciones observadas cuando se realiza un test con los Controles de Calidad LumiraDx HbA1c no invalidan los resultados previos obtenidos con los Test LumiraDx.

Servicio al cliente de LumiraDx:

Para cualquier consulta sobre el producto, póngase en contacto con el **servicio de atención al cliente de LumiraDx**, llamando al **0800 5847239** o por correo electrónico: customerservice@lumiradx.com. Puede encontrar más información en www.lumiradx.com.

Inspección de Verpackung in en Inhalt von de Qualität Kontrollen vor dem Gebrauch auf Beschädigung. Meld eventuelle schade an de Kundendienst von LumiraDx en gebrauch de kit mit des schade wort waargenomen aan de inhoud.

De Quality Controls zijn uitsluitend bestemd voor professioneel gebruik.

Política de devolución:

Si hay un problema con los Controles de Calidad LumiraDx HbA1c, se le puede solicitar que los devuelva. Antes de devolver el producto, debe obtener un número de autorización de devolución del servicio de atención al cliente de LumiraDx. Este número de autorización de devolución debe figurar en la caja de envío utilizada para la devolución. Por lo tanto, las devoluciones ordenadas después de la activación, póngase en contacto con el servicio de atención al cliente de LumiraDx usando los anteriores datos de contacto.

Garantía limitada

ESPAÑOL

lumiraDx™ Controles de calidad HbA1c

Solo para uso profesional

REF L0608010103 IVD

SPEC-35868 R1

ART-02674 R1 Fecha de revisión 08/2022

Los Controles de Calidad LumiraDx HbA1c (en adelante, Control de Calidad) son controles de calidad opcionales que se utilizan con el LumiraDx Instrument (en adelante, el Instrument) y el Test HbA1c (en adelante, el Test HbA1c).

Leas estas instrucciones en su totalidad antes de utilizar los Controles de Calidad.

Inspeccione de Verpackung in en Inhalt von de Qualität Kontrollen vor dem Gebrauch auf Beschädigung. Meld eventuelle schade an de Kundendienst von LumiraDx en gebrauch de kit mit des schade wort waargenomen aan de inhoud.

De Quality Controls zijn uitsluitend bestemd voor professioneel gebruik.

Beoogde gebruik

De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.

De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.

Overzicht van en toelichting op de test

De LumiraDx HbA1c Quality Controls zijn een optionele quality control voor het Instrument bij gebruik met de LumiraDx HbA1c Test. De Quality Control-toestellen is bestemd voor medische doeleinden, voor gebruik in een laboratorium, om de betrouwbaarheid te schakelen en systematische afwijkingen in de detectie te kunnen ontlasten als gevolg van variatie van magnitude of analytische instrumenten en kan worden gebruikt voor laboratoriumtoelating. Het Quality Control-toestel wordt bevestigd door uw organisatie en de testfrequentie wordt bepaald door plaatselijke richtlijn.

Reagentia:

Elas Quality Control bevat menselijk volbloed, stabilisator en een gespecificeerd niveau van glycosylende hemoglobine (HbA1c). De Quality Control-toestellen worden beregenen door de LumiraDx HbA1c Test. De gestalte van de LumiraDx HbA1c Testtip zijn individueel geïdentificeerd met een referentiemerkende voor de meting van HbA1c van de internationale federatie voor klinische chemie en laboratoriumgeneeskunde (International Federation of Clinical Chemistry and Laboratory Medicine, IFCC).

Waarschuwungen en voorzorgsmaatregelen:

- Voor gebruik bij in-vitro diagnose
- Deze controle bevat materiaal van menselijke oorsprong dat is gelijst en niet-toegankelijk te worden voor antilichamen tegen het immuunresponsysteem (EIV 1 en 2), hepatitis B-antipartikel-antigeen (HbAg) en hepatitis-C-virus (antiHCV) in het donorschuld.Dit product moet, in een laboratorium, om de betrouwbaarheid te schakelen en systematische afwijkingen in de detectie te kunnen ontlasten als gevolg van variatie van magnitude of analytische instrumenten en kan worden gebruikt voor laboratoriumtoelating. Het Quality Control-toestel wordt bevestigd door uw organisatie en de testfrequentie wordt bepaald door plaatselijke richtlijn.
- De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.
- Pas de normale voorzorgsmaatregelen toe die vereist zijn voor het hanteren van alle laboratoriumreagentia.
- Alle onderdelen van deze kit kunnen worden afgeworpen als biologisch gevaarlijk afval volgens de lokale richtlijn.
- Ze het veiligheidsinformatieblad bij het product voor risico- en veiligheidsinformatie en informatie over de oever. Het veiligheidsinformatieblad bij het product is verkrijgbaar op lumiradx.com.
- De eisen van de lokale bevoegde vergunning- of accreditatie-entiteit moeten worden gatgelegd in de quality controlprogramma.

Oplag en stabiliteit:

- De controle is op bij een temperatuur tussen 2 °C en 8 °C (36 °F-46 °F). **NIEF INVRIJZEN.**
- Laat het LumiraDx Instrument op kamertemperatuur komen (15 °C - 30 °C / 59 °F - 86 °F) gedurende tenminste 10 minuten (maar niet langer dan twee (2) uur) voorafgaand aan het gebruik.
- Ongedrukt controle die worden opgeslagen tussen 2 °C en 8 °C (36 °F-46 °F) worden gebruikt tot de uitvervaldatum.
- Controles zijn in opening 30 dagen lang stabiel tussen 2 °C en 8 °C (36 °F-46 °F).

Geleverde materialen:

- 3 x 0,5 mL flocans met gestabiliseerd volbloed voor Quality Control niveau 1
- 3 x 0,5 mL flocans met gestabiliseerd volbloed voor Quality Control niveau 2
- 40 x 20 µL, plastic overbrengingspipetten met één bol (voor eenmalig gebruik)
- 40 x 20 µL, plastic overbrengingspipetten met één bol (voor eenmalig gebruik)

Versteite benodigdheden die niet in de Quality Control-doos zijn ingeprengd

- LumiraDx Instrument
- LumiraDx HbA1c Teststrips
- LumiraDx Connect - als connectiviteit vereist is (zie de gebruikershandleiding van LumiraDx Connect)
- Bijlifter met Quality Control-toestellen (in de doos met HbA1c Teststrips)

Gereedmaken voor het testen:

U hebt het LumiraDx Instrument nodig evenals de volgende benodigdheden:

- Tias Reactives LumiraDx HbA1c
- Controles de Calidad LumiraDx HbA1c Nivel 1 o Nivel 2
- Pipetas de transferencia de plástico de una ampolla (de un solo uso)

Preparación de los Controles de Calidad:

Los Controles de Calidad líquidos se suministran listos para su uso.

Manipulación de las Tiras Reactivas LumiraDx HbA1c:

Para estar seguros de utilizar correctamente el test HbA1c e el Instrument, leo el prospecto de la Tira Reactiva HbA1c correspondiente e el manual del usuario de la Piattaform.

Controles de Calidad Nivel 2

Unidad de medida	Media	DE	% CV	N
% HbA1c	9,4	0,27	2,9	870

Limitaciones:

Este producto está diseñado como un Control de Calidad realizado en la LumiraDx Platform para HbA1c. El resultado del Control de Calidad está sujeto a las limitaciones de la Piattaform de medición. Las desviaciones pueden indicar posibles problemas con uno o más componentes de la Piattaform de análisis. El LumiraDx Instrument y las Tiras Reactivas LumiraDx HbA1c tienen características integradas para detectar errores y evitar resultados falsos cuando se realiza el análisis. Por lo tanto, las desviaciones observadas cuando se realiza un test con los Controles de Calidad LumiraDx HbA1c no invalidan los resultados previos obtenidos con los Test LumiraDx.

Servicio al cliente de LumiraDx:

Para cualquier consulta sobre el producto, póngase en contacto con el **servicio de atención al cliente de LumiraDx**, llamando al **0800 5847239** o por correo electrónico: customerservice@lumiradx.com. Puede encontrar más información en www.lumiradx.com.

Inspección de Verpackung in en Inhalt von de Qualität Kontrollen vor dem Gebrauch auf Beschädigung. Meld eventuelle schade an de Kundendienst von LumiraDx en gebrauch de kit mit des schade wort waargenomen aan de inhoud.

De Quality Controls zijn uitsluitend bestemd voor professioneel gebruik.

Política de devolución:

Si hay un problema con los Controles de Calidad LumiraDx HbA1c, se le puede solicitar que los devuelva. Antes de devolver el producto, debe obtener un número de autorización de devolución del servicio de atención al cliente de LumiraDx. Este número de autorización de devolución debe figurar en la caja de envío utilizada para la devolución. Por lo tanto, las devoluciones ordenadas después de la activación, póngase en contacto con el servicio de atención al cliente de LumiraDx usando los anteriores datos de contacto.

Garantía limitada

Los Controles de Calidad LumiraDx HbA1c (en adelante, Control de Calidad) son controles de calidad opcionales que se utilizan con el LumiraDx Instrument (en adelante, el Instrument) y el Test HbA1c (en adelante, el Test HbA1c).

Leas estas instrucciones en su totalidad antes de utilizar los Controles de Calidad.

Inspeccione de Verpackung in en Inhalt von de Qualität Kontrollen vor dem Gebrauch auf Beschädigung. Meld eventuelle schade an de Kundendienst von LumiraDx en gebrauch de kit mit des schade wort waargenomen aan de inhoud.

De Quality Controls zijn uitsluitend bestemd voor professioneel gebruik.

Beoogde gebruik

De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.

De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.

Overzicht van en toelichting op de test

De LumiraDx HbA1c Quality Controls zijn een optionele quality control voor het Instrument bij gebruik met de LumiraDx HbA1c Test. De Quality Control-toestellen is bestemd voor medische doeleinden, voor gebruik in een laboratorium, om de betrouwbaarheid te schakelen en systematische afwijkingen in de detectie te kunnen ontlasten als gevolg van variatie van magnitude of analytische instrumenten en kan worden gebruikt voor laboratoriumtoelating. Het Quality Control-toestel wordt bevestigd door uw organisatie en de testfrequentie wordt bepaald door plaatselijke richtlijn.

Reagentia:

Elas Quality Control bevat menselijk volbloed, stabilisator en een gespecificeerd niveau van glycosylende hemoglobine (HbA1c). De Quality Control-toestellen worden beregenen door de LumiraDx HbA1c Test. De gestalte van de LumiraDx HbA1c Testtip zijn individueel geïdentificeerd met een referentiemerkende voor de meting van HbA1c van de internationale federatie voor klinische chemie en laboratoriumgeneeskunde (International Federation of Clinical Chemistry and Laboratory Medicine, IFCC).

Waarschuwungen en voorzorgsmaatregelen:

- Voor gebruik bij in-vitro diagnose
- Deze controle bevat materiaal van menselijke oorsprong dat is gelijst en niet-toegankelijk te worden voor antilichamen tegen het immuunresponsysteem (EIV 1 en 2), hepatitis B-antipartikel-antigeen (HbAg) en hepatitis-C-virus (antiHCV) in het donorschuld.Dit product moet, in een laboratorium, om de betrouwbaarheid te schakelen en systematische afwijkingen in de detectie te kunnen ontlasten als gevolg van variatie van magnitude of analytische instrumenten en kan worden gebruikt voor laboratoriumtoelating. Het Quality Control-toestel wordt bevestigd door uw organisatie en de testfrequentie wordt bepaald door plaatselijke richtlijn.
- De LumiraDx HbA1c Quality Controls zijn bedoeld voor gebruik door laboratoriumpersoneel/zorgverleners in een laboratorium opgesteld met de LumiraDx Platform. Het gebruik van de Quality Controls voor gebruik in de huisartsenpraktijk wordt niet ondersteund.
- Pas de normale voorzorgsmaatregelen toe die vereist zijn voor het hanteren van alle laboratoriumreagentia.
- Alle onderdelen van deze kit kunnen worden afgeworpen als biologisch gevaarlijk afval volgens de lokale richtlijn.
- Ze het veiligheidsinformatieblad bij het product voor risico- en veiligheidsinformatie en informatie over de oever. Het veiligheidsinformatieblad bij het product is verkrijgbaar op lumiradx.com.
- De eisen van de lokale bevoegde vergunning- of accreditatie-entiteit moeten worden gatgelegd in de quality controlprogramma.

Oplag en stabiliteit:

- De controle is op bij een temperatuur tussen 2 °C en 8 °C (36 °F-46 °F). **NIEF INVRIJZEN.**
- Laat het LumiraDx Instrument op kamertemperatuur komen (15 °C - 30 °C / 59 °F - 86 °F) gedurende tenminste 10 minuten (maar niet langer dan twee (2) uur) voorafgaand aan het gebruik.
- Ongedrukt controle die worden opgeslagen tussen 2 °C en 8 °C (36 °F-46 °F) worden gebruikt tot de uitvervaldatum.
- Controles zijn in opening 30 dagen lang stabiel tussen 2 °C en 8 °C (36 °F-46 °F).

Geleverde materialen:

- 3 x 0,5 mL flocans met gestabiliseerd volbloed voor Quality Control niveau 1
- 3 x 0,5 mL flocans met gestabiliseerd volbloed voor Quality Control niveau 2
- 40 x 20 µL, plastic overbrengingspipetten met één bol (voor eenmalig gebruik)
- 40 x 20 µL, plastic overbrengingspipetten met één bol (voor eenmalig gebruik)

Versteite benodigdheden die niet in de Quality Control-doos zijn ingeprengd

- LumiraDx Instrument
- LumiraDx HbA1c Teststrips
- LumiraDx Connect - als connectiviteit vereist is (zie de gebruikershandleiding van LumiraDx Connect)
- Bijlifter met Quality Control-toestellen (in de doos met HbA1c Teststrips)

Gereedmaken voor het testen:

U hebt het LumiraDx Instrument nodig evenals de volgende benodigdheden:

- Tias Reactives LumiraDx HbA1c