

# lumiraDx<sup>®</sup> HbA1c Quality Controls

## For Professional Use Only

REF: L0608010103 IVD  
SPEC-36760 R2  
ART-03533 R2 Date of Rev 2024-03

### Expected Values:

The LumiraDx HbA1c Quality Control approximate target values and ranges can be found in the below table:

	Target Value	Acceptable Range
Quality Control Level 1	34 mmol/mol 5.3% HbA1c	29 mmol/mol – 40 mmol/mol 4.8% HbA1c – 5.8% HbA1c
Quality Control Level 2	92 mmol/mol 10.6% HbA1c	80 mmol/mol – 104 mmol/mol 9.5% HbA1c – 11.7% HbA1c

Note: LumiraDx HbA1c Quality Control target values and ranges are not Test Strip lot-specific.

### LumiraDx HbA1c Quality Controls:

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 in 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 for 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 used and the Quality Controls correctly, read the appropriate Platform User Manual, the specific assay Test Product Insert 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 tests:**  
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 intended 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 stabilizer, and a specified level of glycated Haemoglobin (HbA1c). The Quality Control reagents 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.  
This control contains 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 Virus (Anti-HCV) of the donor stage. The product, as with all human blood specimens, should be handled as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.  
This Control contains «1» antimicrobial agents and stabilizers. Avoid ingestion or contact with skin or mucous membranes in case of skin contact. Wash affected area with copious amount of water. Seek medical attention if skin irritation occurs. In case of contact with eyes, or if ingested, seek immediate medical attention.  
Exercise the normal precautions required for handling all laboratory reagents.  
All components of this 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.

**Uncollectable results:**  
If the result is not within the acceptable range, the instrument will display an out-of-range result as a Fail to resolve out-of-range results or error messages, check for the following:  
- Controls may be expired or were stored improperly.  
- After removing the Test Strip from the foil pouch, it should be used immediately.  
- Do not open the **door while the test is in progress**. The touch-screen will indicate test progress.  
- If these guidelines are followed and assistance is still required, contact LumiraDx Customer Services, contact details available at lumiraDx.com.  
- Refer to the How-to-use training video at lumiraDx.com.

**Performance characteristics:**  
Quality Control precision was determined for the LumiraDx HbA1c Quality Controls using the LumiraDx HbA1c Test. The results were generated using multiple instruments and multiple vials of Quality Control materials.  
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	5.8	0.12	2.1	84

**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 10 minutes (but not more than 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 with Level 1 Quality Control stabilised whole blood  
- 3 x 0.5 mL vials with Level 2 Quality Control stabilised whole blood  
- 40 x 20 µL 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)

**Getting ready to test:**  
You will need the LumiraDx Instrument and the following supplies:  
- LumiraDx HbA1c Test Strip(s)  
- LumiraDx HbA1c Quality Controls Level 1 or Level 2  
- Single-Bub Plastic Transfer Pipettes (single use)

**Preparing the Quality Controls:**  
The liquid Quality Controls are supplied ready to use.

**Handling the LumiraDx HbA1c Test Strips:**  
To ensure that you are using the HbA1c Test and the instrument correctly, read the appropriate HbA1c Test Strip Product Insert and Platform User Manual.

**LumiraDx Customer Service:**  
For product enquiries, please contact LumiraDx Customer Services on 0800 5844729 or by email: [customerservice@lumiraDx.com](mailto:customerservice@lumiraDx.com). Further information can be found on [www.lumiraDx.com](http://www.lumiraDx.com).

**Return policy:**  
If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning the product, please obtain a return authorization number from LumiraDx Customer Service. This return authorization number must be on the shipping carton 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 (i) of good quality and free of material defects, (ii) functional in accordance with the instructions referenced in the pack insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). The product fails to meet the requirements of the limited warranty then, as the customer's sole remedy, LumiraDx shall either 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's maximum liability with any customer claim that is not covered by the limited warranty shall be the customer. Neither party shall be

liable to the other party for direct, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party provides 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.

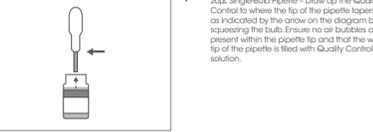
When transferring the Quality Control solution from the vial to the Test Strip, a transfer pipette (or equivalent) should not be used when the Quality Control solution is used. The Quality Controls should be applied directly from the vial to the sample application area of the Test Strip. No 'no-bleed' step is required to run LumiraDx HbA1c Quality Control Test.

Please be advised that the following Transfer Pipettes are acceptable for use with the LumiraDx HbA1c Quality Control solution:

- 20µL Single-Bub Plastic Transfer Pipettes (single use)
- Calibrated Laboratory Pipette (set to 20µL with appropriate tips)

Please note that any transfer pipettes used with the LumiraDx HbA1c Quality Controls should never contain any coatings, additives, surfactant or preservatives.

- Open a Quality Control vial taking care also to remove the rubber stopper.
- Aspirate 20µL of the Quality Control solution from the vial to a pipette type one of the following methods:



20µL Single-Bub Pipette – Draw up the Quality Control to where the tip of the pipette tapers as indicated by the arrow on the diagram by squeezing the bulb. Ensure no air bubbles are present within the pipette tip and that the volume tip of the pipette is filled with Quality Control solution.



Calibrated Laboratory Pipette – Follow the applicable manufacturer's recommendations for correctly aspirating exactly 20µL of Quality Control solution.

3. **Immediately apply the Quality Control solution to the already inserted Test Strip.** Hold the pipette over the Sample Application Area of the Test Strip and dispense a single, large drop (20µL) of the Quality Control solution to the sample application area of the test strip. The sample will then be drawn by capillary action into the Test Strip. When the sample is detected, the instrument will sound (if sounds are enabled) and a confirmation message will be displayed. Dispose of pipette in the appropriate clinical waste. Ensure the rubber stopper is replaced immediately.

4. **Do not open the door while the test is in progress.** The touch-screen will indicate test progress.  
5. **The result will appear on the instrument touch-screen** within approximately 5 minutes of applying the sample and starting the test. The results will be displayed as test value, acceptable range, PASS or FAIL on the test screen.

6. **Dispose of the Test Strip and transfer pipette (or laboratory pipette tip) in the appropriate clinical waste.**  
7. **NOTE:** If you need to repeat a Quality Control Test, use a new Test Strip and transfer pipette/pipette tip.

**Expected results:**  
The instrument displays the test value, acceptable range and Pass or Fail. The result is automatically saved in the memory of the instrument. The system is working properly, and all handling has been done correctly when the test results obtained are within the acceptable control range.

**Uncollectable results:**  
If the result is not within the acceptable range, the instrument will display an out-of-range result as a Fail to resolve out-of-range results or error messages, check for the following:  
- Controls may be expired or were stored improperly.  
- After removing the Test Strip from the foil pouch, it should be used immediately.  
- Do not open the **door while the test is in progress**. The touch-screen will indicate test progress.  
- If these guidelines are followed and assistance is still required, contact LumiraDx Customer Services, contact details available at lumiraDx.com.  
- Refer to the How-to-use training video at lumiraDx.com.

**Performance characteristics:**  
Quality Control precision was determined for the LumiraDx HbA1c Quality Controls using the LumiraDx HbA1c Test. The results were generated using multiple instruments and multiple vials of Quality Control materials.  
The HbA1c results are shown in the following units of measurement:  
- mmol/mol (IFCC)  
- %HbA1c (NGSP)

The HbA1c results are shown in the following units of measurement:

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.8	0.12	2.1	84

**Quality Control Level 1**

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.8	0.12	2.1	84

**Quality Control Level 2**

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	10.6	0.14	1.3	84

**Limitations:**  
This 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 have on-board controls to detect errors and prevent false results when analysis is performed. Therefore, deviations observed when testing with the LumiraDx HbA1c Quality Controls would not invalidate previous results obtained from HbA1c tests.

**Preparation of the Quality Controls:**  
The liquid Quality Controls are supplied ready to use.

**Handling the LumiraDx HbA1c Test Strips:**  
To ensure that you are using the HbA1c Test and the instrument correctly, read the appropriate HbA1c Test Strip Product Insert and Platform User Manual.

**LumiraDx Customer Service:**  
For product enquiries, please contact LumiraDx Customer Services on 0800 5844729 or by email: [customerservice@lumiraDx.com](mailto:customerservice@lumiraDx.com). Further information can be found on [www.lumiraDx.com](http://www.lumiraDx.com).

**Return policy:**  
If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning the product, please obtain a return authorization number from LumiraDx Customer Service. This return authorization number must be on the shipping carton 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 (i) of good quality and free of material defects, (ii) functional in accordance with the instructions referenced in the pack insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). The product fails to meet the requirements of the limited warranty then, as the customer's sole remedy, LumiraDx shall either 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's maximum liability with any customer claim that is not covered by the limited warranty shall be the customer. Neither party shall be

liable to the other party for direct, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party provides 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.

When transferring the Quality Control solution from the vial to the Test Strip, a transfer pipette (or equivalent) should not be used when the Quality Control solution is used. The Quality Controls should be applied directly from the vial to the sample application area of the Test Strip. No 'no-bleed' step is required to run LumiraDx HbA1c Quality Control Test.

Please be advised that the following Transfer Pipettes are acceptable for use with the LumiraDx HbA1c Quality Control solution:

- 20µL Single-Bub Plastic Transfer Pipettes (single use)
- Calibrated Laboratory Pipette (set to 20µL with appropriate tips)

Please note that any transfer pipettes used with the LumiraDx HbA1c Quality Controls should never contain any coatings, additives, surfactant or preservatives.

- Open a Quality Control vial taking care also to remove the rubber stopper.
- Aspirate 20µL of the Quality Control solution from the vial to a pipette type one of the following methods:



20µL Single-Bub Pipette – Draw up the Quality Control to where the tip of the pipette tapers as indicated by the arrow on the diagram by squeezing the bulb. Ensure no air bubbles are present within the pipette tip and that the volume tip of the pipette is filled with Quality Control solution.



Calibrated Laboratory Pipette – Follow the applicable manufacturer's recommendations for correctly aspirating exactly 20µL of Quality Control solution.

3. **Immediately apply the Quality Control solution to the already inserted Test Strip.** Hold the pipette over the Sample Application Area of the Test Strip and dispense a single, large drop (20µL) of the Quality Control solution to the sample application area of the test strip. The sample will then be drawn by capillary action into the Test Strip. When the sample is detected, the instrument will sound (if sounds are enabled) and a confirmation message will be displayed. Dispose of pipette in the appropriate clinical waste. Ensure the rubber stopper is replaced immediately.

4. **Do not open the door while the test is in progress.** The touch-screen will indicate test progress.  
5. **The result will appear on the instrument touch-screen** within approximately 5 minutes of applying the sample and starting the test. The results will be displayed as test value, acceptable range, PASS or FAIL on the test screen.

6. **Dispose of the Test Strip and transfer pipette (or laboratory pipette tip) in the appropriate clinical waste.**  
7. **NOTE:** If you need to repeat a Quality Control Test, use a new Test Strip and transfer pipette/pipette tip.

**Expected results:**  
The instrument displays the test value, acceptable range and Pass or Fail. The result is automatically saved in the memory of the instrument. The system is working properly, and all handling has been done correctly when the test results obtained are within the acceptable control range.

**Uncollectable results:**  
If the result is not within the acceptable range, the instrument will display an out-of-range result as a Fail to resolve out-of-range results or error messages, check for the following:  
- Controls may be expired or were stored improperly.  
- After removing the Test Strip from the foil pouch, it should be used immediately.  
- Do not open the **door while the test is in progress**. The touch-screen will indicate test progress.  
- If these guidelines are followed and assistance is still required, contact LumiraDx Customer Services, contact details available at lumiraDx.com.  
- Refer to the How-to-use training video at lumiraDx.com.

**Performance characteristics:**  
Quality Control precision was determined for the LumiraDx HbA1c Quality Controls using the LumiraDx HbA1c Test. The results were generated using multiple instruments and multiple vials of Quality Control materials.  
The HbA1c results are shown in the following units of measurement:  
- mmol/mol (IFCC)  
- %HbA1c (NGSP)

The HbA1c results are shown in the following units of measurement:

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.8	0.12	2.1	84

**Quality Control Level 1**

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.8	0.12	2.1	84

**Quality Control Level 2**

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	10.6	0.14	1.3	84

**Limitations:**  
This 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 have on-board controls to detect errors and prevent false results when analysis is performed. Therefore, deviations observed when testing with the LumiraDx HbA1c Quality Controls would not invalidate previous results obtained from HbA1c tests.

**Preparation of the Quality Controls:**  
The liquid Quality Controls are supplied ready to use.

**Handling the LumiraDx HbA1c Test Strips:**  
To ensure that you are using the HbA1c Test and the instrument correctly, read the appropriate HbA1c Test Strip Product Insert and Platform User Manual.

**LumiraDx Customer Service:**  
For product enquiries, please contact LumiraDx Customer Services on 0800 5844729 or by email: [customerservice@lumiraDx.com](mailto:customerservice@lumiraDx.com). Further information can be found on [www.lumiraDx.com](http://www.lumiraDx.com).

**Return policy:**  
If there is a problem with the LumiraDx HbA1c Quality Controls you may be asked to return them. Before returning the product, please obtain a return authorization number from LumiraDx Customer Service. This return authorization number must be on the shipping carton 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 (i) of good quality and free of material defects, (ii) functional in accordance with the instructions referenced in the pack insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). The product fails to meet the requirements of the limited warranty then, as the customer's sole remedy, LumiraDx shall either 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's maximum liability with any customer claim that is not covered by the limited warranty shall be the customer. Neither party shall be

## FRANÇAIS

# lumiraDx<sup>®</sup> Contrôles qualité HbA1c

## Réservez à un usage professionnel

REF: L0608010103 IVD  
SPEC-36760 R2  
ART-03533 R2 Date de révision 2024-03

### Valeurs attendues :

Les valeurs et intervalles cibles approximatives du contrôle qualité LumiraDx HbA1c se trouvent dans le tableau ci-dessous :

	Valeur cible	Intervalle acceptable
Contrôle qualité de niveau 1	34 mmol/mol 5.3 % HbA1c	29 mmol/mol – 40 mmol/mol 4.8 % HbA1c – 5.8 % HbA1c
Contrôle Qualité de niveau 2	92 mmol/mol 10.6 % HbA1c	80 mmol/mol – 104 mmol/mol 9.5 HbA1c – 11.7 HbA1c

Remarque : Les valeurs et intervalles cibles du contrôle qualité LumiraDx HbA1c ne sont pas spécifiques au lot de carte microfluidique de test.

### Contrôles qualité HbA1c LumiraDx :

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

Lisez attentivement ces instructions avant d'utiliser les Contrôles qualité.

Avant utilisation, inspecter l'emballage des Contrôles qualité et le contenu pour s'assurer qu'il n'y a pas de endommagement. Signaler tout endommagement ou service clientèle de LumiraDx et ne pas utiliser le kit si le contenu est substantiellement endommagé.

**Intended Use:**  
Les Contrôles qualité HbA1c LumiraDx sont destinés à être utilisés par des professionnels de laboratoire de santé dans le cadre de tests de contrôle qualité automatisés effectués sur l'instrument LumiraDx avec la Carte Microfluidique HbA1c LumiraDx. Les Contrôles qualité permettent aux utilisateurs de confirmer que le dispositif fonctionne conformément aux spécifications.

**Usage prévu :**  
Les Contrôles qualité HbA1c LumiraDx sont destinés à être utilisés par des professionnels de laboratoire de santé dans le cadre de tests de contrôle qualité automatisés effectués sur l'instrument LumiraDx avec la Carte Microfluidique HbA1c LumiraDx. Les Contrôles qualité permettent aux utilisateurs de confirmer que le dispositif fonctionne conformément aux spécifications.

3. **Appliquez immédiatement la solution de Contrôle qualité sur la Carte Microfluidique déjà insérée.** Tenez la pipette au-dessus de la zone d'application de l'échantillon de la Carte Microfluidique et déposez 20 µL de la solution de Contrôle qualité sur la zone d'application de l'échantillon de la Carte Microfluidique. L'échantillon est ensuite aspiré par capillarité dans la Carte Microfluidique. L'instrument émet un son lorsque l'échantillon (si les notifications sonores sont activées) et un message de confirmation est affiché. Éliminer la pipette avec les déchets biologiques appropriés. S'assurer que le bouchon en caoutchouc est immédiatement remis en place.

4. **Ne pas ouvrir la porte pendant que le test est en cours.** L'écran tactile indique la progression du test.

5. **Le résultat s'affiche sur l'écran tactile de l'instrument** dans un délai d'environ 5 minutes après l'application de l'échantillon et le démarrage du test. Les résultats sont présentés sous forme de valeur de test et d'intervalle acceptable ou comme PASS (RÉUSSITE) ou FAIL (ÉCHEC) sur l'écran de l'instrument.

6. **Refer to the manual of utilization of the Platform, to notice the test specific and the safety instructions.** Read the instructions of the Platform and notice the test specific and the safety instructions. The Quality Controls are intended for professional use only.

**Manufacturer information:**  
LumiraDx UK Ltd  
Dunmyr Business Park, Alfoa, FK10 2PL UK  
Registration number: 09206123

**EC REP:**  
LumiraDx AB, Västra Vågen SA, 16961 Solna, Sweden

**CE mark applies to LumiraDx Instrument, Test Strips, Quality Controls and Connect Hub only.**

LumiraDx B.V. Loosdrecht 20 6041 LE, The Netherlands

**Storage and stability:**  
- Stocker les Contrôles à une température comprise entre 2 °C et 8 °C (36 et 46 °F). **NE PAS CONGELER.**  
- Laissez le matériel de Contrôle qualité s'équilibrer à la température ambiante (15 à 30 °C ; 59 et 86 °F) pendant au moins 10 minutes (mais pas plus de 2 heures) avant utilisation.  
- Les Contrôles non ouverts conservés à une température comprise entre 2 °C et 8 °C (36 et 46 °F) peuvent être utilisés jusqu'à la date de péremption.  
- Les contrôles sont stables pendant 30 jours entre 2 °C et 8 °C (36 et 46 °F) après ouverture.

**Materials provided:**

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	5.8	0.12	2.1	84

**Materials required but not provided with the Quality Controls quality**

Unit of Measurement	Mean	SD	%CV	N
%HbA1c	10.6	0.14	1.3	84

**Preparation of the Quality Controls:**  
The liquid Quality Controls are supplied ready to use.

**Handling the LumiraDx HbA1c Test Strips:**  
To ensure that you are using the HbA1c Test and the instrument, take note of the Cards Microfluidiques HbA1c in the manual of utilization of the Platform correspondants.

**Service client LumiraDx :**  
Pour toute question concernant le produit, contactez le service client lumiraDx au 0800 5844729 ou par courrier électronique: [customerservice@lumiraDx.com](mailto:customerservice@lumiraDx.com). Des informations complémentaires sont disponibles sur le site [www.lumiraDx.com](http://www.lumiraDx.com).

**Politique de retour :**  
En cas de problème avec les Contrôles qualité HbA1c LumiraDx, il est possible que leur retour soit demandé. Avant tout retour de produit, obtenez un numéro d'autorisation de retour auprès du service clientèle LumiraDx. Ce numéro d'autorisation de retour doit être indiqué sur le carton d'expédition des produits retournés. Pour les retours ordinaires après l'achat, contactez le service clientèle afin d'obtenir les conditions.

## FRANÇAIS

# lumiraDx<sup>®</sup> Contrôles qualité HbA1c

## Réservez à un usage professionnel

REF: L0608010103 IVD  
SPEC-36760 R2  
ART-03533 R2 Date de révision 2024-03

### Valeurs attendues :

Les valeurs et intervalles cibles approximatives du contrôle qualité LumiraDx HbA1c se trouvent dans le tableau ci-dessous :

	Valeur cible	Intervalle acceptable
Contrôle qualité de niveau 1	34 mmol/mol 5.3 % HbA1c	29 mmol/mol – 40 mmol/mol 4.8 % HbA1c – 5.8 % HbA1c
Contrôle Qualité de niveau 2	92 mmol/mol 10.6 % HbA1c	80 mmol/mol – 104 mmol/mol 9.5 HbA1c – 11.7 HbA1c

Remarque : Les valeurs et intervalles cibles du contrôle qualité LumiraDx HbA1c ne sont pas spécifiques au lot de carte microfluidique de test.

# lumiraDx® Controlli di Qualità HbA1c

Solo per uso professionale

REF: L0608011003 IVD

SPCC-36740 R2 ART-03533 R2 Data di revisione 2024-03

## Valori attesi:

I valori target e gli intervalli approssimati del Controllo Qualità LumiraDx HbA1c sono riportati nella tabella seguente:

	Valore target	Intervallo accettabile
Controllo Qualità livello 1	34 mmol/mol 5,3% HbA1c	29 mmol/mol – 40 mmol/mol 4,8% HbA1c – 5,8% HbA1c
Controllo Qualità livello 2	92 mmol/mol 10,6% HbA1c	80 mmol/mol – 104 mmol/mol 9,5% HbA1c – 11,7% HbA1c

**Note:** I valori target e gli intervalli del Controllo Qualità LumiraDx HbA1c sono riportati nella tabella seguente.

## Controlli di Qualità LumiraDx HbA1c

I Controlli di Qualità LumiraDx HbA1c (di seguito indicati come "Controlli di Qualità") sono controllati di qualità optional da utilizzare con LumiraDx Instrument (di seguito indicato come "Instrument") e il Test LumiraDx HbA1c (di seguito indicato come "Test HbA1c").  
Leggere accuratamente le presenti istruzioni prima di utilizzare i Controlli di Qualità.  
Prima dell'uso, esaminare la confezione e il contenuto dei Controlli di Qualità per escludere la presenza di danni. Separare qualsiasi eventuale danno ad assistenza clienti LumiraDx o non usare il kit qualora si rilevi un qualsiasi danno ai contenuti.  
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 i test di controllo di qualità automatizzati eseguiti su LumiraDx Instrument utilizzato con il Strisce Reattive LumiraDx HbA1c. I Controlli di Qualità ottimizzati agli utilizzatori 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 di Uso della Platform appropriato. Il foglietto illustrativo del test dosaggio specifico e il presente foglietto illustrativo, che, guardando il video di formazione per LumiraDx Platform disponibile su lumiraDx.com, i Controlli di Qualità sono destinati esclusivamente all'uso professionale.

## Sintesi e spiegazione del test

I Controlli di Qualità LumiraDx HbA1c sono controlli di qualità optional per l'Instrument se utilizzato con il Test LumiraDx HbA1c. Gli intervalli del Controllo di Qualità sono assegnati dalla Strisce Reattive LumiraDx HbA1c. Il risultato di ogni controllo di qualità può essere visualizzato automaticamente in un sistema analitico per almeno la precisione e rilevare deviazioni analitiche sistematiche che possono essere causate dal reagente o da variazioni del sistema analitico. Tale materiale può essere usato per il prove interlaboratorio o come 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, stabilizzatori e un livello specifico di emoglobina glicosilata (HbA1c). Gli intervalli del Controllo di Qualità sono assegnati dalla Strisce Reattive LumiraDx HbA1c. Le prestazioni della Strisce Reattive LumiraDx HbA1c sono accoppiati 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 contro il virus dell'immunodeficienza umana (HIV 1 e 2), contro l'antigene di superficie dell'epatite B (HBsAg) e contro il virus dell'epatite C (anti-HCV) talo stato di donatore. Questo prodotto, come tutti i materiali a contatto di origine umana, deve essere trattato come potenziale infettivo e con le appropriate precauzioni di sicurezza del laboratorio, di fine di ridurre al minimo il rischio di trasmissione di malattie infettive.
- Questo controllo contiene <1% di anticorpi anticancro e stabilizzatori. Evitare l'ingestione o il contatto con pelle e mucose. In caso di contatto con la pelle, sciacquare l'area colpita con abbondante acqua e sapone. In caso di contatto con gli occhi, lavare con acqua abbondante e irrigare con soluzione fisiologica sterile. In caso di ingestione, richiedere assistenza medica immediata.
- Adottare le normali precauzioni richieste per la manipolazione di altri reagenti di laboratorio.
- Tutti i componenti di questo prodotto possono essere smaltiti come rifiuti a rischio biologico nel rispetto delle linee guida locali.
- Consultare la scheda di sicurezza del prodotto per le fasi di rischio e di sicurezza e le informazioni per lo smaltimento. La scheda di sicurezza del prodotto è disponibile su lumiraDx.com.
- Non programmare di controllo di qualità del centro è necessario integrare i requisiti dell'organismo di accreditamento o di qualifica 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 - 87 °F) per almeno 10 minuti (ma non oltre due (2) ore) prima dell'uso.
- I controlli 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 0,6 mL biale di sangue intero stabilizzato con Controllo di Qualità livello 1
- 3 x 0,5 mL biale di sangue intero stabilizzato con Controllo di Qualità livello 2
- 40 x 20 µL pipette di trasferimento o 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 di uso di LumiraDx Connect)

**Preparazione del test**  
Saranno necessari i LumiraDx Instrument e i seguenti materiali:  

- Strisce Reattive LumiraDx HbA1c
- Controlli di Qualità LumiraDx HbA1c livello 1 o livello 2
- Pipette di trasferimento o bulbo singolo in plastica (monouso)

**Preparazione dei Controlli di Qualità**  
I Controlli di Qualità quali sono forniti pronti all'uso.

Il presente prodotto è concepito come Controllo di Qualità eseguito dalla LumiraDx Platform per HbA1c. I risultati del Controllo di Qualità sono soggetti alle limitazioni di test della Platform. Le deviazioni possono includere la presenza di problemi con uno o più componenti del test bulk Platform. Il LumiraDx Instrument e il Strisce Reattive LumiraDx HbA1c sono controllati di qualità che permettono di rilevare errori e prevenire risultati falsi quando si verificano i guasti. Pertanto, le deviazioni osservate quando si eseguono i test con i Controlli di Qualità LumiraDx HbA1c non invalidano i precedenti risultati ottenuti con i test LumiraDx.

**Assistenza clienti LumiraDx**  
Per domande relative al prodotto, contattare l'assistenza clienti LumiraDx al numero 0800 5847239 o all'indirizzo email: [customerservice@lumiraDx.com](mailto:customerservice@lumiraDx.com). Ulteriori informazioni sono disponibili sul sito [www.lumiraDx.com](http://www.lumiraDx.com).

Qualsiasi evento avverso verificatosi durante l'uso di questo prodotto o/a problemi di qualità dovranno essere segnalati all'assistenza clienti LumiraDx utilizzando le informazioni di contatto sopra indicate.

**Politica dei resi**  
In caso di problemi con i Controlli di Qualità LumiraDx HbA1c, è possibile che ne sia richiesta la restituzione. Prima di restituire un prodotto è necessario contattare l'assistenza clienti LumiraDx, un numero di autorizzazione di reso. Questo numero dovrà essere riportato sulla scatola di spedizione per la restituzione. Per le restituzioni ordinarie in seguito all'acquisto, offriamo l'assistenza clienti per informazioni sui termini e le condizioni.

## Garanzia limitata

Controlli di Qualità LumiraDx - In base alla durata di conservazione.

Per il periodo di validità della garanzia, LumiraDx garantisce che tutti i prodotti saranno (i) di buona qualità ed esseri 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"). Questo è un prodotto non soddisfabile i requisiti della garanzia limitata, qualsiasi garanzia di commerciabilità, idoneità a scopi particolari o non violazione 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 ritenuto responsabile verso il compratore per danni speciali, accidentali o consequenziali, inclusi, senza limitazioni, perdite di affari, profitti, dati o ricavi, anche nel caso in cui la parte interessata fosse previamente informata della possibilità dei verificarsi di tali danni.

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 di uso della LumiraDx Platform, nel foglietto illustrativo del LumiraDx Test o foglietto illustrativo del pack Controllo di Qualità HbA1c, come anche in seguito a frodi, manomissioni, sollecitazioni fisiche inaspettate, negligenza o incidenti. Qualsiasi richiesta di risarcimento da parte del cliente di sensi della garanzia limitata dovrà essere presentata per iscritto entro il periodo di validità della garanzia limitata.

**Glossario dei simboli**

Simbolo	Significato
	Limite di temperatura
	Fabbricatore
	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.
	Conformità del Regno Unito valutata ai sensi dei Medical Devices Regulations 2002 (SI 2002 n. 618 e successive modifiche) o FAL (NON RUSCITC)
	Indica un materiale di controllo previsto per verificare le caratteristiche prestazionali del lumiraDx Instrument. Un'indicazione del livello del controllo è riportata sulla scatola, ad es. 1 o 2.
	Indica che il materiale di Controllo di Qualità sono associati potenziali rischi biologici.
	Consultare le istruzioni per l'uso
	Mandatario nell'Unione Europea
	Indica un contenitore con le informazioni sull'identificatore univoco del dispositivo

**Info** "Marchio CE" Questo prodotto soddisfa i requisiti della Direttiva europea 98/79/CE sui dispositivi medici diagnostici in vitro.

**UK CA** Conformità del Regno Unito valutata ai sensi dei Medical Devices Regulations 2002 (SI 2002 n. 618 e successive modifiche) o FAL (NON RUSCITC)

**CONTROL** Indica un materiale di controllo previsto per verificare le caratteristiche prestazionali del lumiraDx Instrument. Un'indicazione del livello del controllo è riportata sulla scatola, ad es. 1 o 2.

**Biohazard** Indica che il materiale di Controllo di Qualità sono associati potenziali rischi biologici.

**Information** Consultare le istruzioni per l'uso

**EC REP** Mandatario nell'Unione Europea

**UDI** Indica un contenitore con le informazioni sull'identificatore univoco del dispositivo

**Info** "Marchio CE" Questo prodotto soddisfa i requisiti della Direttiva europea 98/79/CE sui dispositivi medici diagnostici in vitro.

**UK CA** Conformità del Regno Unito valutata ai sensi dei Medical Devices Regulations 2002 (SI 2002 n. 618 e successive modifiche) o FAL (NON RUSCITC)

**CONTROL** Indica un materiale di controllo previsto per verificare le caratteristiche prestazionali del lumiraDx Instrument. Un'indicazione del livello del controllo è riportata sulla scatola, ad es. 1 o 2.

**Biohazard** Indica che il materiale di Controllo di Qualità sono associati potenziali rischi biologici.

**Information** Consultare le istruzioni per l'uso

**EC REP** Mandatario nell'Unione Europea

**UDI** Indica un contenitore con le informazioni sull'identificatore univoco del dispositivo

**Info** "Marchio CE" Questo prodotto soddisfa i requisiti della Direttiva europea 98/79/CE sui dispositivi medici diagnostici in vitro.

**UK CA** Conformità del Regno Unito valutata ai sensi dei Medical Devices Regulations 2002 (SI 2002 n. 618 e successive modifiche) o FAL (NON RUSCITC)

**CONTROL** Indica un materiale di controllo previsto per verificare le caratteristiche prestazionali del lumiraDx Instrument. Un'indicazione del livello del controllo è riportata sulla scatola, ad es. 1 o 2.

**Biohazard** Indica che il materiale di Controllo di Qualità sono associati potenziali rischi biologici.

**Information** Consultare le istruzioni per l'uso

**EC REP** Mandatario nell'Unione Europea

**UDI** Indica un contenitore con le informazioni sull'identificatore univoco del dispositivo

## ESPAÑOL

### Procedimiento/realización de un test:

Consulte el manual de usuario de la LumiraDx Platform para obtener instrucciones sobre cómo analizar un muestra de Control de Calidad. Abra la bolsa de aluminio de la Tira Reactiva HbA1c justo antes de usarlo e inserte la Tira Reactiva en el LumiraDx Instrument. El Instrument indicará cuándo estará listo para la aplicación de la muestra.

Una vez que se ha extraído la Tira Reactiva de la bolsa de aluminio, debe utilizarse inmediatamente. No utilice la Tira Reactiva una vez que haya pasado el tiempo de validez de uso. Después de usar la Tira Reactiva, la realización de un test de Control de Calidad LumiraDx HbA1c no requiere un paso de tiempo de lista.

Tenga en cuenta que las pipetas de transferencia siguientes son aceptables para el uso con la solución de Control de Calidad LumiraDx HbA1c:

Valor objetivo	Rango aceptable
34 mmol/mol 5,3% HbA1c	29 mmol/mol – 40 mmol/mol 4,8% HbA1c – 5,8% HbA1c
92 mmol/mol 10,6% HbA1c	80 mmol/mol – 104 mmol/mol 9,5% HbA1c – 11,7% HbA1c

**Nota:** Los valores objetivo e intervalos del Control de Calidad LumiraDx HbA1c no son específicos del lote de HbA1c reactivos.

**Controles de Calidad LumiraDx HbA1c:**  
Los Controles de Calidad LumiraDx HbA1c (en adelante, Controles de Calidad) son controles de calidad opcionales que se utilizan con el LumiraDx Instrument (en adelante, el Instrument) y el Test LumiraDx HbA1c (en adelante, el Test HbA1c).  
Lea estas instrucciones en su totalidad antes de utilizar los Controles de Calidad.

Inspeccione el paquete de Controles de Calidad y su contenido antes de utilizarlos para detectar cualquier daño. No utilice los materiales si encuentra algún daño. No utilice el kit si el contenido presenta daños.

Los Controles de Calidad están indicados únicamente para uso profesional.

**Uso previsto:**  
Los Controles de Calidad LumiraDx HbA1c están indicados para el uso por parte de profesionales de laboratorio y sanitarios para realizar tests de control de calidad automatizados en el LumiraDx Instrument, cuando este se uso con la Tira Reactiva LumiraDx HbA1c. Los Controles de Calidad permiten garantizar a los usuarios que el dispositivo funciona dentro de las especificaciones.

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

## Controles de calidad HbA1c

### Procedimiento/realización de un test:

Consulte el manual de usuario de la LumiraDx Platform para obtener instrucciones sobre cómo analizar un muestra de Control de Calidad. Abra la bolsa de aluminio de la Tira Reactiva HbA1c justo antes de usarlo e inserte la Tira Reactiva en el LumiraDx Instrument. El Instrument indicará cuándo estará listo para la aplicación de la muestra.

Una vez que se ha extraído la Tira Reactiva de la bolsa de aluminio, debe utilizarse inmediatamente. No utilice la Tira Reactiva una vez que haya pasado el tiempo de validez de uso. Después de usar la Tira Reactiva, la realización de un test de Control de Calidad LumiraDx HbA1c no requiere un paso de tiempo de lista.

Tenga en cuenta que las pipetas de transferencia siguientes son aceptables para el uso con la solución de Control de Calidad LumiraDx HbA1c:

Valor objetivo	Rango aceptable
34 mmol/mol 5,3% HbA1c	29 mmol/mol – 40 mmol/mol 4,8% HbA1c – 5,8% HbA1c
92 mmol/mol 10,6% HbA1c	80 mmol/mol – 104 mmol/mol 9,5% HbA1c – 11,7% HbA1c

**Nota:** Los valores objetivo e intervalos del Control de Calidad LumiraDx HbA1c no son específicos del lote de HbA1c reactivos.

**Controles de Calidad LumiraDx HbA1c:**  
Los Controles de Calidad LumiraDx HbA1c (en adelante, Controles de Calidad) son controles de calidad opcionales que se utilizan con el LumiraDx Instrument (en adelante, el Instrument) y el Test LumiraDx HbA1c (en adelante, el Test HbA1c).  
Lea estas instrucciones en su totalidad antes de utilizar los Controles de Calidad.

Inspeccione el paquete de Controles de Calidad y su contenido antes de utilizarlos para detectar cualquier daño. No utilice los materiales si encuentra algún daño. No utilice el kit si el contenido presenta daños.

Los Controles de Calidad están indicados únicamente para uso profesional.

**Uso previsto:**  
Los Controles de Calidad LumiraDx HbA1c están indicados para el uso por parte de profesionales de laboratorio y sanitarios para realizar tests de control de calidad automatizados en el LumiraDx Instrument, cuando este se uso con la Tira Reactiva LumiraDx HbA1c. Los Controles de Calidad permiten garantizar a los usuarios que el dispositivo funciona dentro de las especificaciones.

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

**Info** "Marchio CE" Este producto cumple los requisitos de la Directiva Europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro.

**UK CA** Conformidad para el EU evaluado bajo los Reglamentos para productos sanitarios 2002 (SI 2002 n. 618, con enmiendas) (UK MDR 2002)

**CONTROL** Indica un material de control que está destinado a verificar las características de rendimiento del lumiraDx Instrument. En el cuadro se indica el nivel del control, por ejemplo, 1 o 2

**Biohazard** Indica que hay posibles riesgos biológicos asociados con el material de Control de Calidad

**Information** Consulte las instrucciones de uso

**EC REP** Representante autorizado en la Unión Europea

**UDI** Indica un portador que contiene la información de identificador único de producto

## Controles de calidad HbA1c

### Procedimiento/realización de un test:

Consulte el manual de usuario de la LumiraDx Platform para obtener instrucciones sobre cómo analizar un muestra de Control de Calidad. Abra la bolsa de aluminio de la Tira Reactiva HbA1c justo antes de usarlo e inserte la Tira Reactiva en el LumiraDx Instrument. El Instrument indicará cuándo estará listo para la aplicación de la muestra.

Una vez que se ha extraído la Tira Reactiva de la bolsa de aluminio, debe utilizarse inmediatamente. No utilice la Tira Reactiva una vez que haya pasado el tiempo de validez de uso. Después de usar la Tira Reactiva, la realización de un test de Control de Calidad LumiraDx HbA1c no requiere un paso de tiempo de lista.

Tenga en cuenta que las pipetas de transferencia siguientes son aceptables para el uso con la solución de Control de Calidad LumiraDx HbA1c:

Valor objetivo	Rango aceptable
34 mmol/mol 5,3% H	