P0600307

Instructions For Use
Hemoglobin A1c Calibrator Set

CE

Revised in November, 2019

CAUTION：US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

1. Intended Use

The Hemoglobin A1c Calibrator Set is a reference agent specifically designed for calibrating Tosoh Automated Glycohemoglobin Analyzers (HLC-723®G7, HLC-723G8, HLC-723GX and HLC-723G11) which use stable A_{1c} (s-A_{1c}) when performing assay operations.
For detailed description of procedures for using the Hemoglobin A1c Calibrator Set, refer to the Operator's Manuals for the Tosoh Automated Glycohemoglobin Analyzers (HLC-723G7, HLC-723G8, HLC-723GX(*) or HLC-723G11(*)).

(*) CAUTION：The HLC-723GX and HLC-723G11 analyzers are not for sale in the US.

2. Prior to Use

Inspect the packaging and the exterior of the vial for any signs of damage prior to use. If any damage is visible, contact your local Tosoh sales representative.
Confirm that the following document is included in the package.

- Instructions For Use 1 copy
- Barcode Sheets 1 copy

3. Warnings and Precautions

1) This product is intended for *in vitro* diagnostic use only.
2) The analyzer must be recalibrated, using fresh Calibrators if a peak is detected between s-A_{1c} and A_0.
3) Each human blood used in the preparation of the Hemoglobin A1c Calibrator Set has been tested by standard, approved methods and found to be negative for the presence of HBsAg and antibodies to HIV and HCV. Since no test method can give complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that this product be handled with the same precautions as those used for patient samples.

4. Content

Catalogue No.	Description	Package content
0018767	Hemoglobin A1c Calibrator Set	10 × 4 mL (5 each of 2 levels)

5. Related Components

	Catalogue No.
Hemoglobin A1c Control Set	0021974

6. Storage and Stability

1) The Hemoglobin A1c Calibrator Set should be stored at 2 to 8 °C while unopened. It will remain stable for use up to the expiration date indicated on the vial.
2) After being opened and reconstituted, the Hemoglobin A1c Calibrator Set will remain stable for use for up to one week at 2 to 8 °C.
3) The expiration date for the Hemoglobin A1c Calibrator Set is shown below.
Expiration date: ****-**-** (YYYY-MM-DD)

7. Assigned Values

Hemoglobin A1c Calibrator Set
Lot No. ******

IFCC(*1) Aligned Value

	Calibrator (1)	Calibrator (2)
IFCC Aligned Value	**.* mmol/mol	**.* mmol/mol

(*1) IFCC：International Federation of Clinical Chemistry and Laboratory Medicine

The assigned values are traceable to IFCC HbA1c Calibrator Set provided from IFCC Working Group on Standardization of HbA_{1c}.

NGSP(*2) Aligned Value

NGSP Aligned Value	Calibrator (1)	Calibrator (2)
HLC-723G11(*3)	*.** %	**.** %
HLC-723G8		
HLC-723GX(*3)		
HLC-723G7 (Ver. 3.00 ~)(*4)		
HLC-723G7	*.* %	**.* %

(*2) NGSP：National Glycohemoglobin Standardization Program
(*3) The HLC-723GX and HLC-723G11 analyzers are not for sale in the US.
(*4) HLC-723G7 can set two decimal places after the system version 3.00.

The assigned values were calculated using the following conversion equation:

NGSP (%) = 0.09148 × IFCC (mmol/mol) + 2.152

Ref.：Geistanger A. et al. Statistical Methods for Monitoring the Relationship between IFCC Reference Measuring Procedure for Hemoglobin A1c and the Designed Comparison Methods in the United States, Japan, and Sweden. Clin Chem 54：1379-1385, 2008

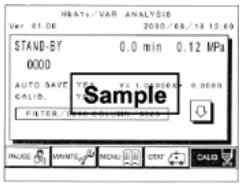
8. Reconstitution Procedure

1) Remove the cap from the calibrator vial.
2) Reconstitute Calibrators (1) and (2) by adding 4 mL of distilled water to each and thoroughly blending using inverted gentle agitation.
3) Store the reconstituted calibrators at 2 to 8 °C and use within a period of one week.

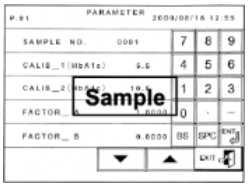
9. Calibration Procedure

HLC-723G7

1) Dispense 800 µL, respectively, of reconstituted Calibrators (1) and (2) into the designated sample cups.
2) Place Calibrators (1) and (2) in positions No. 1 and No. 2 of the first rack.
3) Go to Main screen and press the CALIB key so that it is highlighted in reverse. In Main screen confirm that CALIB status is "Yes".



4) Go to Main screen, press the MENU key to open MENU screen and PARAMETER key to open PARAMETER screen.



CAUTION：The numbers shown above are just examples. Please enter the numbers shown at "7. Assigned Values".

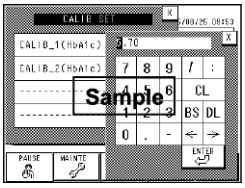
5) Enter the assigned values for Calibrators (1) and (2) (See "7. Assigned Values") at CALIB_1 and CALIB_2, respectively.
6) Press the START key. Calibrator (1) will be automatically measured three times and Calibrator (2) will be automatically measured two times to calculate calibration coefficients "a" and "b". This will, in turn, calibrate subsequent samples using those calibration coefficients. Note that calibration will have to be performed again if the following results are produced.
・ Difference between the 2nd and 3rd s-A_{1c} (%) value exceeds 0.3 %.
・ Difference between the 4th and 5th s-A_{1c} (%) value exceeds 0.3 %.
・ Any of the four calibrator results differ from its assigned value by 30 % or more.

Refer to the HLC-723G7 Operator's Manual for detailed description.

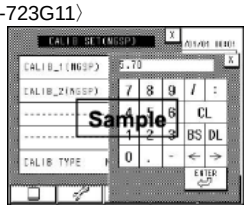
HLC-723G8 / HLC-723GX / HLC-723G11

1) ・HLC-723G8
Dispense 400 µL, reconstituted Calibrators (1) and (2), respectively, into the designated sample cups.
・HLC-723GX / HLC-723G11
In the case of HLC-723GX and HLC-723G11 dispense 500 µL, reconstituted Calibrators (1) and (2), respectively, into the designated sample cups.
2) ・HLC-723G8 / HLC-723G11
Place Calibrators (1) and (2) in positions No. 1 and No. 2 of the first rack.
・HLC-723GX
Place Calibrators (1) and (2) in each Calibrator holder on the sampler turntable.
3) Press the CALIB key on Main screen (No. 1 screen).
4) The key is highlighted and the Calibrator's assigned value input screen (CALIB SET screen) is displayed.
The lists of assigned values for Calibrators (1) and (2) (See "7. Assigned Values") will be shown.
5) Press record for Calibrator (1) to pop up the number input screen. Enter the assigned value and close the screen.

〈HLC-723G8〉



〈HLC-723GX / HLC-723G11〉



CAUTION : The numbers shown above are just examples. Please enter the numbers shown at "7. Assigned Values".

6) Enter the assigned value for Calibrator (2) as well.
7) Confirm that the correct values are entered.
8) Close CALIB SET screen.
9) Press the START key. Calibrator (1) will be automatically measured three times and Calibrator (2) will be automatically measured two times to calculate calibration coefficients "a" and "b". This will, in turn, calibrate subsequent samples using those calibration coefficients. Note that calibration will have to be performed again if the following results are produced.
・Difference between the 2nd and 3rd s-A_{1c} (%) value exceeds 0.3 %.
・Difference between the 4th and 5th s-A_{1c} (%) value exceeds 0.3 %.
・Any of the four calibrator results differ from its assigned value by 30 % or more.

Refer to the HLC-723G8, HLC-723GX or HLC-723G11 Operator's Manual for detailed description.

Hemoglobin A1c Calibrator Barcode Sheets
(For use with HLC-723G11 only.)
Calibrator's assigned value, Lot. No. and expiration date are automatically entered by scanning Barcode Sheets with an optional handy barcode scanner connected to HLC-723G11.

Refer to the HLC-723G11 Operator's Manual for detailed description.

10. Sample Measurement

Note that the measured values displayed in the chromatograms for individual measuring procedures may differ from the foregoing assigned values.

〈HLC-723G7〉

〈HLC-723G8〉

〈HLC-723GX〉

〈HLC-723G11〉

EU rev. A1CAL-0400303

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bg Инструкции за употреба на различни езици са на разположение на нашия уебсайт: www.tosohbioscience.eu в раздела Помощ и поддръжка (Service & Support). Хартиено копие може да бъде получено на fax +32 13 66 47 49 или е mail: info.raga.eu@tosoh.com Актуална Версия: A1CAL-0400303
⚠ Този продукт съдържа материали с човешки или животински произход и трябва да бъде третиран като потенциално инфекциозен.

cs Návod k použití v různých jazycích je dostupný na našich webových stránkách: www.tosohbioscience.eu v sekci " Service & Support " . Tištěnou verzi můžete obdržet faxem číslo +32 13 66 47 49, nebo e mailem: info.raga.eu@tosoh.com. Aktuální Verze: A1CAL-0400303
⚠ Tento výrobek obsahuje materiály pocházející ze zvířat nebo od lidí a je třeba s nimi zacházet jako s potenciálně infekčními.

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⚠ Το προϊόν αυτό περιέχει υλικό ανθρώπινης ή ζωικής προέλευσης και θα πρέπει να αντιμετωπίζεται ως δυνητικά μολυσματικό.

en Instructions For Use in multiple languages are available on our website: www.tosohbioscience.eu under the" Service & Support" section. A paper version can be obtained by fax +32 13 66 47 49 or e mail: info.raga.eu@tosoh.com. Actual Version: A1CAL-0400303
⚠ This product contains human or animal source materials and should be treated as potentially infectious.

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⚠ Este producto contiene tejidos de origen humano o animal y debe ser tratado como producto potencialmente infeccioso.

et Eri keeltes kasutusjuhendid on saadaval meie veebilehel: www.tosohbioscience.eu sisajaotuses "Service & Support" . Paberkandjal versiooni saab tellida faksinumbril +32 13 66 47 49 või e posti teel: info.raga.eu@tosoh.com. Kehtiv Versioon: A1CAL-0400303
⚠ See toode sisaldab inim- või loomse päritoluga aineid ning võib olla nakkuschtlik.

fr Les instructions d' utilisation sont disponibles en plusieurs langues sur notre site web: www.tosohbioscience.eu, dans la rubrique « Service & Support ». Vous pouvez obtenir un exemplaire papier par fax, au n° +32 13 66 47 49, ou par e mail, à l' adresse : info.raga.eu@tosoh.com. Version Actuelle : A1CAL-0400303
⚠ Ce produit contient des substances animales ou humaines et doit, par conséquent, être traité comme un produit potentiellement infectieux.

hr Upute za uporabu na više jezika dostupne su na našem web-mjestu: www.tosohbioscience.eu u odjeljku „Service & Support" (Usluga i podrška). Papirnata verzija može dobiti putem faksa +32 13 66 47 49 ili e-poštom: info.raga.eu@tosoh.com. Stvarna verzija: A1CAL-0400303
⚠ Ovaj proizvod sadrži materijale ljudskog ili životinjskog podrijetla i trebao bi se tretirati kao da je potencijalno zarazan.

hu A Használati utasítás több nyelven elérhető webszájtunkon: www.tosohbioscience.eu, a „Service & Support " (Szolgáltatás és Támogatás) szekció alatt. Nyomtatott változat igényelhető faxon a +32 13 66 47 49-es telefonszámon vagy e mailben: info.raga.eu@tosoh.com. Aktuális Változat: A1CAL-0400303
⚠ Ez a termék emberi vagy állati forrásanyagokat tartalmaz, ezért lehetségesen fertőzőként kell kezelni.

it Istruzioni per l' Uso in diverse lingue sono disponibili sul nostro sito web www.tosohbioscience.eu alla sezione "Service & Support " . Versione cartacea può essere richiesta via fax al +32 13 66 47 49 o via e mail a info.raga.eu@tosoh.com. Versione Attuale: A1CAL-0400303
⚠ Il prodotto contiene materiali di origine umana o animale e va trattato come potenzialmente infettivo.

lt Naudojimo instrukcijas įvairiomis kalbomis galite rasti mūsų tinklalapio www.tosohbioscience.eu skyriuje „Service & Support " . Popierinę versiją galite gauti faksu +32 13 66 47 45 arba el. paštu info.raga.eu@tosoh.com. Naujausia Versija: A1CAL-0400303
⚠ Šiame gaminyje yra žmogaus arba gyvūnų kilmės medžiagų, tad elkitės taip, tarsi jie galėtų sukelti infekciją.

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⚠ Šis produkts satur cilvēku vai dzīvnieku izejmateriālus un ir uzskatāms par potenciāli infekciju saturošu.

no Brukerveiledninger for flere språk er tilgjengelig på våre nettsider: www.tosohbioscience.eu under seksjonen "Service & Support". Du kan få tilsendt en papirversjon ved å sende en faks til +32 13 66 47 49, eller en e-post til: info.raga.eu@tosoh.com. Gjeldende versjon: A1CAL-0400303
⚠ Dette produktet kan inneholde kildematerialer fra mennesker eller dyr, og må behandles som potensielt smittefarlig.

pl Instrukcja Użytkowania w różnych językach jest dostępna na naszej stronie internetowej: www.tosohbioscience.eu w zakładce „Service & Support " (Serwis i Wsparcie). O wersję papierową można pytać pod nr faksu: +32 13 66 47 49 lub e mailem: info.raga.eu@tosoh.com. Aktualna Wersja: A1CAL-0400303
⚠ Produkt zawiera materiał pochodzenia ludzkiego lub zwierzęcego i dlatego należy go traktować jako potencjalnie zakaźny.

pt As instruções de utilização encontram-se disponíveis em diversos idiomas no nosso sítio: www.tosohbioscience.eu na secção "Service & Support (Serviços e Assistência). Pode ainda obter uma versão em papel através do fax +32 13 66 47 49 ou do email: info.raga.eu@tosoh.com. Versão Actual: A1CAL-0400303
⚠ Este produto contém materiais de origem humana ou animal e deve ser tratado como potencialmente infeccioso.

ro Instrucţiuni de utilizare în diverse limbi sunt disponibile pe site ul nostru: www.tosohbioscience.eu, la secţiunea "Service & Support" (Service şi asistenţă tehnică). O versiune pe hârtie poate fi obtinută comandând o prin fax, la +32 13 66 47 49, sau prin e mail, la info.raga.eu@tosoh.com. Versiune Actuală: A1CAL-0400303
⚠ Acest produs conţine materiale de provenienţă umană sau animală şi trebuie tratate ca potenţial infecţioase.

sk Návod na použitie vo viacerých jazykoch je dostupný na našej web stránke: www.tosohbioscience.eu v sekcii " Service & Support " . Vytlačenú verziu možno získať faxom +32 13 66 47 49 alebo cez e mail: info.raga.eu@tosoh.com. Aktuálna Verzia: A1CAL-0400303
⚠ Tento výrobok obsahuje materiál z ľudských alebo zvieracích zdrojov a malo by sa s ním zaobchádzať ako s potenciálne infekčným materiálom.

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⚠ Ta izdelek vsebuje materiale človeškega ali živalskega izvora, kar lahko privede do okužb.

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⚠ Denna produkt innehåller material med humant eller animalt ursprung och skall behandlas som potentiellt infektiös.

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⚠ Bu ürün, insan ya da hayvan kaynaklı malzemeler içerebilir ve enfeksiyon olasılığı bulunduğu göz önünde bulundurularak ele alınmalıdır.

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Symbols on the product labels

European Conformity

Manufacturer

EC REP
Authorized representative in the European Community

REF
Catalogue number / Part number

IVD
In vitro diagnostic medical device

Consult instructions for use

Use-by date / Use by

LOT
Batch code / Lot number

Temperature limitation

NET
Net volume (after reconstitution for lyophilized material)

Supplied by
Supplied by

Mfg. site
Actual manufacturing site

Date of manufacture

US: For prescription use only
US: For prescription use only

Imported and Marketed in India by
Imported and Marketed in India by

TOSOH

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