BIO-RAD

Hemoglobin Capillary Collection System (HCCS)

Instructions For Use / Gebrauchsanweisung /
Notice d'utilisation / Istruzioni per l'uso /
Instrucciones de uso / Instruções de utilização /
Användarinstruktioner / Brugsvejledning / Bruksanvisning /
Használati utasítás / Návod k použití / Instrukcja użycia /
Návod na použitie / Οδηγίες Χρήσης /
Instruções de Uso / Инструкции за употреба / Upute za uporabu

REF **196-2051**	Σ **5**
REF **196-2052**	Σ **100**
REF **196-2053**	Σ **5000**

CE IVD

***UNITED STATES**, Bio-Rad Laboratories, Inc., 4000 Alfred Nobel Drive, Hercules, CA 94547*
EC REP ***FRANCE**, Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette*

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Made in France

SYMBOLS LEXICON

	EC REP	LOT
Manufacturer Hersteller Fabricant Produttore Fabricante Fabricante Tillverkare Producent Produsent Gyártó Výrobce Producent Výrobca Κατασκευαστής Fabricante Производител Proizvođač	Authorized Representative in the European Union Bevollmächtigter in der Europäischen Union Représentant agréé pour l'Union européenne Rappresentante autorizzato per l'Unione Europea Representante autorizado en la Unión Europea Representante Autorizado na União Europeia Auktoriserad EU-representant Autoriseret repræsentant i EU Autorisert representant i EU Meghatalmazott képviselő az Európai Unióban Zplnomocněný zástupce v Evropském společenství Autoryzowany przedstawiciel na terenie Unii Europejskiej Autorizovaný zástupca v Európskej únii Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση Representante autorizado na União Europeia Упълномощен представител в Европейския съюз Ovlašteni predstavnik u Europskoj uniji	Lot Number Chargenbezeichnung N° de lot Numero di lotto N.º de lote Número do lote Batchnummer Lotnummer Lotnummer Tételszám Číslo šarže Numer serii Číslo šarže Αριθμός παρτίδας Número do lote Партиден номер Broj serije

SYMBOLS LEXICON

 Use by Verwendbar bis À utiliser avant Scadenza Fecha de caducidad Utilizar até Används före Udløbsdato Utløpsdato Felhasználandó: Použít do data Termin ważności Dátum exspirácie Χρήση έως Validade Използвайте до Upotrijebiti do	IVD For In Vitro Diagnostic Use In-vitro-Diagnostikum Pour une utilisation diagnostique in vitro Per uso diagnostico in vitro Para uso en diagnóstico in vitro Para utilização no diagnóstico in vitro För in vitro-diagnostiskt bruk Til in vitro-diagnostisk brug Til in vitro-diagnostisk bruk In vitro diagnosztikai felhasználásra Pro diagnostické použití in vitro Do diagnostyki in vitro Určené na diagnostiku in vitro Για in vitro διαγνωστική χρήση Para uso em diagnóstico in vitro За инвитро диагностика Za in vitro dijagnostiku	 Temperature Limit Temperaturgrenze Limite de température Limite di temperatura Límite de temperatura Limite de temperatura Temperaturgränser Temperaturgrænse Temperaturgrenser Hőmérsékleti határérték Omezení teploty Limit temperatury Teplotný limit Όριο θερμοκρασίας Limite de temperatura Температурна граница Ograničenje temperature

SYMBOLS LEXICON

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ENGLISH

INTENDED USE

The Hemoglobin Capillary Collection System (HCCS) is intended for the collection of human whole blood for the percent determination of hemoglobin A_{1c} using Bio-Rad HPLC methods.

PRINCIPLE OF THE PROCEDURE

Capillary blood is collected in capillaries and hemolyzed in aqueous solution.

FOR ANALYSIS PLEASE NOTE

- Samples can be analyzed immediately after blood collection.
- Sample volume allows injections in duplicate.

TEST COMPONENTS

HEMOGLOBIN CAPILLARY COLLECTION SYSTEM

	Quantity		
	REF 196-2051	REF 196-2052	REF 196-2053
Description	5 Tests	100 Tests	5000 Tests
Sample Preparation Vials. Each containing 1.5 mL of an aqueous solution of EDTA and potassium cyanide (0.25 mmol/L). Store at 15–30 °C.	1 x 5	1 x 100	1 x 5000
Capillaries. Plastic capillaries (5 µL) in a dispenser.	1 x 5	1 x 100	0
Capillary Holder. Holder for manipulating the capillaries.	1	1	0
Labels	5	5 x 20	250 x 20

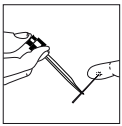
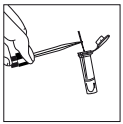
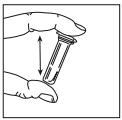
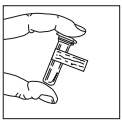
ADDITIONAL ITEMS AVAILABLE FROM BIO-RAD

REF	*Description*
196-2100	**Capillaries,** 20 x 100
196-1054	**Capillary holders,** 20

PRECAUTIONS/WARNINGS

- Please read through and familiarize yourself with the contents of the Instructions for Use before using the test for the first time.
- All personnel performing the test must wear standard laboratory safety apparatus (safety glasses, laboratory coat, gloves, etc.).
- All patient samples should be considered as potential biohazardous material and must be handled as directed by safety regulations of local ordinance.
- The solution in the sample preparation vials contains potassium cyanide which may react with acids. This solution is classified as non-hazardous. Please follow safety regulations of local ordinance. For more information, please refer to the safety data sheet (SDS).
- Waste materials contain potentially infectious sample and potentially dangerous substances deriving from reagents. Treat and dispose of waste material as directed by safety regulations of local ordinance.
- If there is evidence of microbial contamination, discard the vial.
- All items available from Bio-Rad should not be recycled after performing the test unless explicitly specified.

PROCEDURE

1. Clean the surface of the finger with an alcohol (70%) swab.	
2. Induce blood flow using a sterile lancet or similar device (not available from Bio-Rad).	
3. Take one capillary out of the capillary dispenser and attach it in the capillary holder. For safety reasons avoid contamination of the capillary (e.g., by using clean gloves). Fill the capillary with blood (from finger tip). **Important:** The capillary must be filled end-to-end!	
4. Remove any residual blood drops on the outside of the capillary. Transfer the filled capillary into the sample preparation vial.	
5. Cap the vial and shake it to rinse the blood completely from the capillary. **Important:** Make sure that no blood remains in the capillary.	
6. Label the vial with the label provided in the kit. Include the Sample Identification and additional information according to laboratory requirements.	

7. The specimen can now be passed on for analysis or kept refrigerated until shipment. Samples prepared using this procedure are stable for: • two weeks at room temperature or • four weeks at 2–8 °C or • four days at 42 °C. **NOTE:** *Samples can be analyzed immediately after blood collection.* *Sample volume allows injections in duplicate.*	

PERFORMANCE CHARACTERISTICS

The Hemoglobin Capillary Collection System (HCCS) was validated for use with:

REF 270-2101NU	VARIANT II HbA1c Program
REF 12000447	VARIANT II TURBO HbA1c Kit - 2.0
REF 270-2455EX	VARIANT II TURBO HbA1c Kit - 2.0*
REF 270-2500	VARIANT II Dual Program*
REF 290-1004	D-100 HbA1c Analytical Cartridge/Calibrator Pack**

* *International use only: These applications are not available for diagnostic use in the United States.*

** *International use only: HCCS is not cleared for use with D-100 in the United States.*

The Hemoglobin Capillary Collection System (HCCS) was used to collect adult capillary blood, additionally adult venous blood was gathered.

Hemoglobin A_{1c} values of the samples were determined with the VARIANT II HbA_{1c} Program (REF 270-2101NU).

A comparison of capillary blood samples with the corresponding venous blood samples yielded the following linear regression:

n = 31 r = 0,998 y = 1,0 x + 0,0

Further performance data are available on request.

TRADEMARK INFORMATION

Bio-Rad is a trademark of Bio-Rad Laboratories, Inc. in certain jurisdictions.

TECHNICAL ASSISTANCE

In the USA and Puerto Rico: Call toll-free 1-800-2BIORAD (224-6723), available 24 hours a day, 7 days a week.

Outside the USA: Contact your regional Bio-Rad office. Go to www.bio-rad.com for contact information.

Bio-Rad Laboratories, Inc.

Clinical Diagnostics Group

Website *www.bio-rad.com/diagnostics* ***U.S.*** *1-800-224-6723*
Australia *+61(2)9914-2800* ***Austria*** *+43-1-877-8901* ***Belgium*** *+32(3)710-53-00*
Brazil *+55(31)3689-6600* ***Canada*** *1-514-334-4372* ***China*** *+86-21-61698500*
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Greece *+30-210-7774396* ***Hong Kong*** *+852-2789-3300* ***Hungary*** *+36-1-459-6100*
India *+1800-180-1224* ***Israel*** *+972-3-9636050* ***Italy*** *+39-02-216091*
Japan *+81-3-6361-7070* ***Korea*** *+82-2-3473-4460* ***Mexico*** *+52(55)5488-7670*
The Netherlands *+31-318-540666* ***New Zealand*** *+64-9-415-2280*
Norway *+47-23-38-41-30* ***Poland*** *+48-22-3319999* ***Portugal*** *+351-21-472-7700*
Russia *+7-495-721-1404* ***Singapore*** *+65-6415-3170*
South Africa *+27-11-442-85-08* ***Spain*** *+34-91-590-5200*
Sweden *+46-8-555-127-00* ***Switzerland*** *+41(0)26-674-55-05/06*
Taiwan *+886-2-2578-7189* ***Thailand*** *+662-651-8311*
United Kingdom *+44(0)20-8328-2000*