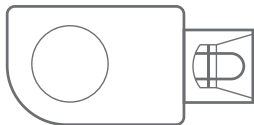


NADAL[®] Hb/Hct plus microcuvette



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INTENDED USE

The NADAL[®] Hb/Hct plus microcuvette, along with the NADAL[®] Hb/Hct plus analyser, is an *in-vitro* diagnostic system for the quantitative measurement of haemoglobin in blood obtained by fingerstick or venipuncture and the subsequent calculation of hematocrit value.

For professional *in-vitro* diagnostic use only.

PRINCIPLE

The NADAL[®] Hb/Hct plus analyser functions as a spectrophotometer, measuring the degree of light absorption within the NADAL[®] Hb/Hct plus microcuvette. The optical distance between the cuvette walls is fixed and allows for photometric determination of the haemoglobin in undiluted blood samples.

WARNINGS AND PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this package insert.
- Do not use contaminated NADAL[®] Hb/Hct plus microcuvette.
- Do not reuse microcuvettes. Instruments used for sample collection should only be used for processing one sample each.
- Ensure that the LOT numbers of all the test components (NADAL[®] Hb/Hct plus microcuvette and ID chip) match.
- After inserting the NADAL[®] Hb/Hct plus microcuvette, ensure that the holder is closed.
- Do not use the test components beyond the expiration date, as this may lead to erroneous test results.
- Prior to testing, bring refrigerated samples to room temperature by allowing them to stand for approximately 30 minutes. For shipping, samples must be packed in accordance with local/national regulations.
- Both NADAL[®] Hb/Hct plus microcuvettes and testing equipment should be kept away from vibrations and/or magnetic fields. With normal usage, it can be observed that the testing equipment causes minor vibrations.
- Used microcuvettes, capillary tubes and sample collection tools should be handled carefully and disposed of using an appropriate method in accordance with relevant local regulations.
- Exposure to larger quantities of sodium azide may cause a number of health issues, including convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.

STORAGE AND STABILITY

The NADAL[®] Hb/Hct plus microcuvettes are stable for up to 24 months, if stored correctly at 15-35 °C (59-95 °F).

TEST SYSTEM LIMITATIONS

- Certain factors may interfere with the test run and lead to erroneous results, including technical/procedural errors, worn out test components or the presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be made in conjunction with the comprehensive judgment of the attending physician, taking into account clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF 1320101

- 200 microcuvettes (4 x 50 pc.)
- 1 ID-Chip
- 1 Package insert

MATERIALS REQUIRED (NOT INCLUDED)

The following items can be purchased separately from nal von minden GmbH. Please contact our sales division for more information.

- NADAL[®] Hb/Hct plus analyser **REF** 1320100
- NADAL[®] Hb/Hct plus controls **REF** 1320103
- NADAL[®] Hb/Hct plus calibrator **REF** 1320104

SAMPLE COLLECTION AND PROCESSING

The test can be performed using human blood obtained by fingerstick or venipuncture.

- It is recommended to test the sample within 24 hours of collection.
- Samples may be stored for up to a week at 2-8 °C (35-46 °F) prior to being tested.

TEST SETUP

- Check the contents of the kit.
- Ensure that the microcuvettes and ID chips have matching LOT numbers.
- Leave refrigerated samples at room temperature for at least 30 minutes prior to carrying out the test. Place the microcuvette on a clean, flat, dust-free surface.
- If using a blood sample obtained by fingerstick, wipe away the first drop of blood with a sterile gauze pad or cotton ball.

TEST PROCEDURE

1. Draw blood obtained by fingerstick into a microcuvette by bringing the cuvette into contact with the blood drop, or otherwise apply 15 µl of whole blood sample into the opening of the microcuvette using a micro-pipette.
2. Wipe off excess blood from the surface of the cuvette using a soft gauze or a sanitised absorption pad.
3. Insert the microcuvette into the microcuvette holder of the NADAL[®] Hb/Hct plus analyser. Make sure you position the microcuvette in the direction of the groove indicated on the holder.
4. Close the holder completely. The reader will run the test automatically. If testing does not begin automatically, open and close the holder again.
5. A beep tone will sound when the test result is ready. Read the test result on the display screen of the NADAL[®] Hb/Hct plus analyser.












TEST RESULT INTERPRETATION












- The NADAL[®] Hb/Hct plus analyser displays haemoglobin concentration of the test sample in terms of 'g/dL', 'g/L' or 'mmol/L'.
- Values above 20.0 g/dL (200 g/L; 12.4 mmol/L) must be confirmed using a suitable laboratory method.

QUALITY CONTROL

- Quality control tests represent *good laboratory practice* by confirming the expected results and validity of the assay, and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test LOT, in order to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.

SYMBOLS

Symbol	DE	EN	FR	ES	DK	PL
	Hersteller	Manufacturer	Fabricant	Fabbricante	Fabrikant	Producent
	Nicht wiederverwenden	Do not reuse	Ne pas réutiliser	No reutilizar	Må ikke genbruges	Tylko do jednorazowego użytku
	Temperaturbegrenzung	Temperature limitation	Limites de température	Limitación de temperatura	Temperaturbegrænsning	Temperatura przechowywania
	<i>In-vitro</i> Diagnostika	<i>In-vitro</i> diagnostic medical device	Dispositif médical de diagnostic <i>in-vitro</i>	Producto sanitario para diagnóstico <i>in-vitro</i>	Medicinsk udstyr til <i>in-vitro</i> diagnostik	Tylko do diagnostyki <i>in-vitro</i>
	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Best il l ingsnummer	Numer katalogowy
	Chargenbezeichnung	Batch code	Code du lot	Código de lote	Batchkode	Numer serii
	CE Konformitätszeichen	CE marking of conformity	Conformité aux normes européennes	Conformidad europea	CE-mærkning	Znak zgodności CE
	Gebrauchsanweisung beachten	Consult instructions for use	Consulter la notice d'utilisation	Consúltense las instrucciones de uso	Se brugsanvisningen	Przestrzegać instrukcji obsługi
	Verwendbar bis	Use by	Utiliser jusqu'au	Fecha de caducidad	Udløbsdato	Data ważności
	Vorsicht	Caution	Mise en garde	Precaución	Advarsel	Uwaga
	Ausreichend für <n> Ansätze	Sufficient for <n> tests	Suffisant pour "n" tests	Suficiente para <n> utilizaciones	Tilstrækkeligt til <n> test	Wystarczający na <n> Powtórzeń

Symbol	PT	CZ	FI	SE	IT	NO	NL
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabbricante	Produsent	Fabrikant
	Não reutilizar	Pro jednorázové použití	Kertakäyttöinen	Får inte återanvändas	Non riutilizzare	Må ikke brukes om igjen	Niet opnieuw gebruiken
	Limites de temperatura	Teplotní omezení	Lämpötilarajat	Temperaturbegrænsning	Limiti di temperatura	Temperaturbegrensning	Temperatuurlimiet
	Dispositivo médico para diagnóstico <i>in-vitro</i>	Diagnostický zdravotnický prostředek <i>in-vitro</i>	<i>In-vitro</i> diagnostiikkaan tarkoitettu lääkinnällinen laite	Medicinteknisk produkt avsedd för <i>in-vitro</i> diagnostik	Dispositivo medico-diagnostico <i>in-vitro</i>	<i>In-vitro</i> diagnostikk medisinsk enhet	Medisch hulpmiddel voor <i>in-vitro</i> diagnostiek
	Número de catálogo	Katalogov éčíslo	Luettelonumero	Listnummer	Riferimento di Catalogo	Katalog nummer	Catalogus nummer
	Código do lote	Kód šarže	Eräkoodi	Satsnummer	Codice lotto	Codice lotto	Code van de partij
	Conformidade com as normas europeias	CE certifikát	CE-merkitty	CE-mærkning	Conformità europea	CE standardisert	CE-markering
	Consultar as instruções de utilização	Viz návod k použití	Katso käyttöohjetta	Läs bruksanvisningen	Consultare le istruzioni per l'uso	Les bruksanvisning nøyte	Raadpleeg de gebruiksaanwijzing
	Prazo de validade	Spotřebujte do	Käytettävä viimeistään	Används före	Utilizzare entro	Tidtaking	Houdbaar tot
	Cuidado	Pozor	varovaisuus	Varning	Attenzione	Forsiktighet	Voorzichtigheid
	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Sufficiente per "n" saggi	Tilstrækkelig for<n> tester	Voldoende voor <n> test

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