

Norma Reagent Packs

(for Icon-3, i3LAB, Icon-5, Icon-5 OP and iVet-5 analyzer)

► **Intended Use and Test Principle** ◀

Norma reagent packs are dedicated sets of reagents intended to be used with Norma's automated hematology analyzers.

The diluent reagent is a buffered, stabilized, and micro-filtered electrolyte solution for automated dilution of blood samples, quantitative determination of red blood cells (RBC), quantitative and qualitative determination of white blood cells (WBC), 3- or 5-part WBC subpopulations, platelets (PLT) and for 3-part analyzers also measurement of hemoglobin (HGB) concentration.

The lyse reagent is a stabilized and micro-filtered lysing agent for stromatolysis of red blood cells (RBC), for quantitative determination of white blood cells (WBC), for WBC 3-part (lymphocytes [LYM], mid-size cells [MID], granulocytes [GRA]) or 5-part (lymphocytes [LYM], monocytes [MON], neutrophils [NEU], eosinophils [EOS], basophils [BAS]) differentiation and hemoglobin (HGB) concentration measurement of human or animal blood.

iSol3 and cleaner reagents are buffered, stabilized, and micro-filtered electrolyte solutions used for conditioning and cleaning of specific tubing sections and chambers.

The reagent packs are intended for near patient and laboratory professional use as an in vitro diagnostic medical device.

► **Reagent Preparation** ◀

The product is ready to use, please follow the installation procedures of this instructions for use.

► **Warnings and Precautions** ◀

- Read instructions for use carefully before use.
- The product is environmentally friendly, azide-free, and does not contain harmful ingredients. The product is classified as non-hazardous in compliance with Regulation (EC) No 1272/2008.
- Do not use the product beyond the expiry date.
- Do not use the product if the primary package is damaged or there is discolouration or floating particles are visible in the liquid.
- Store at the recommended temperature range.
- Do not use the product if it has been frozen or kept at excessive heat. Use the product at room temperature (18-30°C). If it has been stored below 18°C or above 30°C, leave it at normal room temperature for 3 hours before use.
- Users are advised to wear protective clothing when handling chemical products. Wear lab coat, gloves, and eye protection.
- Observe standard laboratory precautions for use and follow national or local health and safety guidelines.
- Avoid contact with eyes, skin, and clothing. In case of contact with eyes or skin, rinse immediately with plenty of water.
- Please refer to the product's Safety Data Sheet.
- Please report any serious incident involving the product to the manufacturer and the competent local authority.

► **Storage and Shelf Life of Reagents** ◀

- Storage temperature range: **2-35°C**.
- Shelf life: **4 years**.
- Open bottle stability: **6 months**.
- Expiry date: **refer to the product's labeling**.

► **Waste Management** ◀

Dispose waste product, unused product, and contaminated packaging in compliance with local regulations.

► **Materials Required but not Provided** ◀

- Norma hematology analyzer.
- Reagent pickup tubes and caps.
- Empty waste container.
- Control and calibrator materials.

► **Reagent Installation Precautions** ◀

- Person installing the reagent must be a trained professional.
- Always keep the reagent in its original container.
- Do not mix leftover reagent with new.
- Use the reagent suction tubes and caps supplied with the analyzer.
- Before putting it into the new reagent, clean the suction tubes to be immersed into the reagent by wiping them from top to the bottom, using lint-free wipe moistened with distilled water. Avoid any dust or microbial contamination of the tubing and reagent.
- Do NOT place the reagent pack above the analyzer or on the ground. Place it on the same level with the analyzer.

► **Connecting the Reagents** ◀

1. Open the reagent pack lid.
2. Open the caps of the bottles in reagent pack.
3. Cut the sealing foil using a clean, sharp object and carefully remove the complete foil from the bottle.
4. After cleaning the suction tube, immerse it into the reagent and tighten the cap. Make sure to match the color on the tube, the cap, and the marking at the back of the analyzer with the correct reagent. **Ensure that reagent tubes are not broken, twisted or blocked.**



Reagent:	Diluent	Lyse	iSol3/Cleaner
Color:	GREEN	YELLOW	WHITE

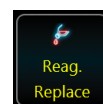
5. Connect an empty waste container with RED cap to the analyzer. Waste container should be placed on the ground.
6. Locate the QR code on the English IFU sheet.
7. Turn on the analyzer and wait for the startup process to finish.
8. **Tap and hold any point on the screen** to access local menu.

OR

Tap menu button in lower right corner of the screen to access local menu.

► **Reagent Replacement using the built-in Wizard (if applicable)** ◀

9. Tap the "Reag. Replace" icon.
10. Follow the steps on the screen.
11. The sequence will end with an automated priming cycle and a Fast Blank measurement. If the Fast Blank is acceptable then the analyzer will display the results and you can use the new reagent.
12. When a new reagent batch is used, verify performance with running control measurements and perform calibration if needed.

► **Reagent Replacement without using the built-in Wizard** ◀






13. Tap the "Read QR" icon. Hold the QR code approximately 10-15 cm (4-6 inches) from the QR/barcode reader or camera. Ensure the QR code is not bent. If the QR code is damaged, use manual data entry.
14. After entering QR code data, the product is ready to use.
15. Run Fast Blank measurement.
16. When a new reagent batch is used, verify performance with running control measurements and if needed perform calibration.



► Limitations ◀

- Each reagent pack is designed to allow running a specified number of tests as mentioned in ► **Product Content and characteristics of Norma Reagent Packs** ◀ section below, under the following conditions:
 - A minimum # of tests are measured daily.
 - Two Fast Blank measurements run daily.
 - The analyzer is turned off at the end of each day.
 - The user performs all maintenance and cleaning operations requested by the software.
- After the certain number of tests – specified by the QR code – no new samples can be measured.
- The amount of leftover reagent inside the reagent pack may vary depending on usage.
- Control, calibrator and patient sample measurements equally reduce the number of tests available.
- If less than the minimum daily samples or more Fast blank measurements are made, this results in a higher relative reagent consumption and the reagent pack may run out of any reagent before the specified number of tests.
- No complaints are accepted in connection with leftover reagents or about the number of tests, if the above listed conditions were not met.

► Explanation of Symbols ◀

REF	Catalogue number	LOT	Batch/LOT number		Permitted storage temperature		CE mark
	Expiry date	IVD	In-vitro diagnostic medical device		See the instructions for use		Manufacturer
CONT	Content						

► Reagent Product Composition (in ion-free water) ◀

Reagent:	iDiI2, iDiI5 iDiI5 OP	iDiI3	Vet Diluent	iLyse2	iLyse3	iLyse5 iLyse5 OP VetLyse	iSol3	iClean5	iClean5 OP VetCleaner
Sodium chloride	< 1.6%	< 1.5%	< 1.4%	< 2.0%	< 1.5%	-	< 1.5%	< 1.5%	< 1.5%
Surfactants	-	-	-	< 3.0%	< 3.5%	< 0.5%	< 1.0%	< 1.1%	< 1.0%
Buffers	< 1.1%	< 1.0%	< 1.1%	< 1.0%	< 1.0%	< 1.8%	< 1.0%	< 1.0%	< 1.0%
Stabilizers	< 1.0%	< 0.5%	< 1.0%	< 0.5%	< 0.5%	< 1.1%	< 0.5%	< 0.9%	< 0.5%
Preservatives	< 0.7%	< 0.5%	< 0.7%	< 0.5%	< 0.5%	< 1.0%	< 0.5%	< 0.8%	< 0.5%

► Product Content and characteristics of Norma Reagent Packs ◀

Reagent pack:	Norma- iRP21	Norma- iRP20	Norma- iRP31	Norma-iRP35	Norma- iRP51	Norma- iRP54	Norma- iRP51 OP	Norma- iRP52 OP	Norma PetPack
Product code	IC-91721	IC-91720	IC-91711	IC-91715	IC-91751	IC-91754	IC-91771	IC-91772	IC-91761
Use with:	i3LAB	i3LAB	Icon-3	Icon-3	Icon-5	Icon-5	Icon-5 OP	Icon-5 OP	iVet-5
# of tests (@ minimum tests/day)	100 (5/day)	1000 (50/day)	100 (3/day)	Closed mode: 500 Open mode: 400 (15/day)	100 (3/day)	400 (15/day)	100 (3/day)	250 (5/day)	100 (3/day)
Diluent*	900 mL	4900 mL	1100 mL	3550 mL	3400 mL	5000 mL	2200 mL	3400 mL	2000 mL
Lyse*	400 mL	1500 mL	350 mL	750 mL	600 mL	1000 mL	580 mL	1000 mL	450 mL
iSol3*	-	-	400 mL	1150 mL	-	-	-	-	-
Cleaner*	-	-	-	-	300 mL	300 mL	1000 mL	1150 mL	750 mL
Total*	1300 mL	6400 mL	1850 mL	5450 mL	4300 mL	6300 mL	3780 mL	5550 mL	3200 mL
IFU	located inside the reagent pack box								
QR Code	located inside the reagent pack box, on the English IFU sheet								

* Nominal fill volume: -0/+10 mL for each bottle.