

Instructions For Use

Boule Quintus Reagents: Quintus 5-part Diluent Quintus 5-part Lyse Quintus 5-part Stopper



Installation Instructions for Quintus Reagents

A detailed description of reagent installation / reagent change can be found in the instrument User Manual under section 2 Installation



Intended Use

The Boule Quintus 5-part Diluent, Quintus 5-part Lyse, and Quintus 5-part Stopper reagents are intended for use with the Quintus hematology analyzer systems.



Storage and stability

The Boule Quintus reagents are stable at least up until the expiration date as shown on labels when stored at a temperature between 4°C and 35°C. Open container stability is 3 months if storage recommendations are followed.

Precautions

- Please read the relevant Safety Data Sheet (SDS) before use. SDSs are available at www.boule.com.
- Quintus 5-part Diluent and Quintus 5-part Lyse are classified as hazardous to health according to CLP [Regulation (EC) no 1272/2008]. The required labeling is given below. Detailed information is given in the SDS.

Boule Quintus 5-part Diluent	
Hazard pictogram	
Signal word	Warning
Hazard codes and statements	H317 May cause an allergic skin reaction.
Precautionary statements	P261 Avoid breathing mist, vapors, or spray. P280 Wear protective gloves. P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P501 Dispose of contents and container to authorized waste disposal facility.
Supplemental information	Contains: REACTION MASS OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2HISOTHIAZOL-3-ONE (3:1)

Boule Quintus 5-part Lyse	
Hazard pictogram	
Signal word	Warning
Hazard codes and statements	H317 May cause an allergic skin reaction. H319 Causes serious eye irritation
Precautionary statements	P264 Wash exposed skin thoroughly after handling. P280 Wear protective gloves and eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P501 Dispose of contents and container to authorized waste disposal facility.
Supplemental information	Contains: REACTION MASS OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2HISOTHIAZOL-3-ONE (3:1)

- Boule Quintus 5-part Stopper is not considered hazardous to health or environment. See SDS for detailed information. Required labeling: **EUH210** Safety data sheet available on request. **EUH208** Contains REACTION MASS OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2HISOTHIAZOL-3-ONE (3:1). May produce an allergic reaction.

Serious Incident

If a serious incident occurs in relation with Boule Medical's product, a notice shall be reported to the distributor, the manufacturer Boule and the competent authority of the Member State in which the user and /or the patient is established

Instructions

1. For proper performance **DO NOT** mix Boule reagents with non-Boule products.
2. It is recommended that the Diluent, the Lyse and the Stopper reagents are placed at the instrument level or below.
3. The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. When this occurs perform the following:
 - a. From the Main menu select [ADVANCED] and then [REAGENTS].

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- b. Select [ENTER NEW REAGENT].
- c. Press the text box under the reagent you will scan in (it will highlight in yellow when activated) and then scan in the barcode from the corresponding reagent container.
- d. Repeat for all applicable reagents.
- e. Press [ENTER NEW REAGENT] to save.
- f. Select [EXIT] to return to the Main menu.
- g. Remove the cap and seal on the new reagent container.
- h. Transfer the reagent level sensor from the used container to the new reagent container.
- i. It is important when transferring the reagent tubing that it is kept clean and inserted into the correct reagent container.
- j. The analyzer is now ready to resume operation or analyze samples. No priming or fill cycle is necessary when putting on a new reagent container, if indicator and warning messages are followed.
- k. Run three (3) BACKGROUND CYCLES to complete the reagent exchange and to check that the background is below the acceptance limit.

You can always refer to your Quintus User Manual for reagent priming or changing.

IMPORTANT! Remember to verify calibration prior to running patient samples e.g., using Boule control material.

Ordering information and service

Contact your local Boule representative for orders and support. Please have the catalogue number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.com

REF	Description	Packaging
1504291	Quintus 5-part Diluent	20 L
1504292	Quintus 5-part Lyse	5 L
1504373	Quintus 5-part Stopper	1 L

