

Revision History

| Classification | Description |
|--------------------------|---|
| New instructions for use | First version of a new instructions for use |
| Correction | Correction of documentation anomalies (minor typographical, grammar, and formatting changes are not included) |
| Technical change | Addition, revision and/or removal of information related to the product |
| Regulatory change | Changes due to regulations, directives, laws and/or registration |
| General change | Implementation of non-technical changes |

Reaction Buffer

REF 67365

| Material number and release version | Change classification | Section of change |
|--|--|--|
| 132123-15 10/2022 | Regulatory change | 1. Intended purpose |
| | | 2. Principles of the procedure |
| | | 3. Materials required but not provided |
| | | 4. Preparation |
| | | 5. Storage |
| | | 6. Warnings and precautions |
| | | 8. Explanation of symbols |
| | | 9. Company address |
| | | Technical change |
| | 2. Principles of the procedure | |
| | 3. Materials required but not provided | |
| | 4. Preparation | |
| | 5. Storage | |
| | General change | 6. Warnings and precautions |
| 8. Explanation of symbols | | |
| Corrections | 6. Warnings and precautions (Chinese part) | |
| | 9. Company address | |

INTENDED PURPOSE

The Reaction Buffer is intended to provide and maintain the reaction environment for IgA Reagent, IgM Reagent, IgG Reagent, Complement C3 Reagent, Complement C4 Reagent, Albumin Reagent, Prealbumin Reagent and Transferrin Reagent manufactured by Aidian Oy. The Reaction Buffer is intended to be used together with the reagents for quantitative assays from serum or plasma specimens, by automated clinical chemistry analysers used by laboratory and/or healthcare professionals in clinical laboratory settings. For *in vitro* diagnostic use.

PRINCIPLES OF THE PROCEDURE

Reaction Buffer provides a reaction environment for IgA Reagent, IgM Reagent, IgG Reagent, Complement C3 Reagent, Complement C4 Reagent, Albumin Reagent, Prealbumin Reagent and Transferrin Reagent manufactured by Aidian Oy. The test principle for each assay is provided in analyte-specific instructions for use. Follow the instructions for the individual assay procedure.

MATERIALS REQUIRED BUT NOT PROVIDED

Reagents, protein calibrators and clinical chemistry analyser are required but not provided.

PREPARATION

Reaction Buffer (0.05 M Tris) is ready for use. Before starting an assay, read and follow the instructions for use for the Reaction Buffer and the reagent used.

STORAGE

Unopened: Stable until the expiry date when stored at 2...8°C.

Opened: Stable for 3 months after the date of opening. Stored at 2...8°C when not in use.












WARNINGS AND PRECAUTIONS

- This Reaction Buffer is only intended to be used with the reagent kits listed in the intended purpose.
- Do not use any vial that has visible evidence of microbial growth.
- Do not use the buffer after the expiry date marked on the vials.
- The buffer contains < 0.1% sodium azide, which is not considered a harmful concentration.
- Sodium azide liberates toxic gas when in contact with acids. Azides may react with metal plumbing forming explosive compounds. Azide build-up can be avoided by flushing with a large volume of water when disposing of the reagents.
- When used in accordance with Good Laboratory Practice, good occupational hygiene and the instructions for use, the reagents supplied should not present a hazard to health.
- In case of a serious incident, please report it to the manufacturer or its representative and/or national authority.

DISPOSAL

- Dispose of contents according to national and local law.
- Materials of the components
Paper: Instruction for use
Plastic: Bottle and bottle cap

EXPLANATION OF SYMBOLS

| | |
|--|---|
|  | <i>In vitro</i> diagnostic medical device |
|  | Catalogue number |
|  | Batch code |
|  | Temperature limitation |
|  | Use by |
|  | Consult instructions for use |
|  | Contents |
|  | Manufacturer |
|  | Date of manufacture |
|  | Buffer |
|  | Contains sodium azide |

Revision history can be found from www.aidian.eu.



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