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Changes: Update of Legal Manufacturer Name;
Deletions: -

LIAISON® XL Cuvettes (REF X0016)

1. INTENDED USE

LIAISON® XL Cuvettes (REF X0016) are In Vitro Diagnostic Accessories and are intended to be used with the LIAISON® XL Analyzer to allow the LIAISON® XL Assays execution.
Cuvettes host the liquid mixture of reagents and samples where the analytical reaction occurs.
Cuvettes cannot be re-used and they shall be discarded upon completion of the assay procedure.
Use only DiaSorin approved cuvettes.

2. MATERIALS PROVIDED

– 1 shipping box contains 4 user boxes.
– Each user box contains 9 clear plastic bags with 200 cuvettes per bag.
– 1800 cuvettes per user box, totalling 7200 single cavity cuvettes per shipping box.
– For additional details such as proper test performance of LIAISON® XL assays consult instructions for use of the assay to be performed.

3. HANDLING

For the description of the proper handling procedure, refer to the LIAISON® XL User Manual.

4. STORAGE

– Unopened at 0-30°C in the original box.
– Do not expose to sunlight or humidity.
– After open, reseal the box to protect the cuvettes from contamination.
– Do not use after the expiration date given on the label.

5. WARNINGS AND PRECAUTIONS FOR USERS

– Observe the normal precautions required for handling all laboratory reagents.
– All waste material should be handled with care and disposed of in accordance with the laboratory guidelines and statutory provisions in force in each Country.
– If material packaging has been damaged upon delivery, please notify DiaSorin representative immediately. In this case, the usage of cuvettes shall be avoided before any approval from DiaSorin.
– Any cuvettes whose cleanness and integrity cannot be ensured (e.g. fallen to the ground) are not to be utilized on the system and should be discarded immediately.
– Only cuvettes coming from user boxes have to be used on the LIAISON® XL Analyzer.
– Cuvettes must not be reused.
– For Professional Use Only.

For EU only: please be aware that any serious incident that has occurred in relation to this IVD medical device should be reported to DiaSorin and the competent authority of the EU Member State in which the user and/or patient is established.

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