

**FIELD SAFETY NOTICE**

**Please read carefully**

Product: LIAISON® Calcitonin  
Part No: 310940  
Lot No: 120773 and 120774

Dear Customer:

Our records indicate that you received one or more DiaSorin LIAISON® Calcitonin kits, catalogue number 310940, lot numbers 120773 and 120774. Results of internal stability testing and subsequent investigation have confirmed that these kit lots over time may recover certain normal patient samples high outside of the normal ranges stated in the Instructions for Use.

Internal Quality Control samples, which span the assay range from 30 pg/ml to 1650 pg/ml, continue to recover within their assigned ranges, and therefore the risk to patient is considered low. Furthermore, Calcitonin assay results should be used in conjunction with other clinical and laboratory data to assist in the diagnosis and management of conditions involving an excess or deficiency of Calcitonin.

Patient results obtained with these kit lots should be carefully evaluated and the appropriate action taken based on individual laboratory protocols.

We recommend that customers stop using these kit lots and destroy any remaining inventory. Replacement product will be provided.

Please complete the section below and return to your local DiaSorin distributor.

Number of kits remaining in your inventory: \_\_\_\_\_

Number of kits destroyed: \_\_\_\_\_

Number of replacement kits requested: \_\_\_\_\_