

Date: October 09, 2007

DIASORIN ADVISORY NOTICE

Dear Customer:

Our records indicate that you received one or more DiaSorin LIAISON ® CEA, catalogue number 314311, lot number 721101.

We regret to inform you that with this lot some patient sera showed overestimated values.

Your laboratory may or may not have observed this phenomenon.

This phenomenon is lot specific and it has not been evidenced in previous lots.

Therefore, unless as part of the laboratory policy these samples have already been confirmed by other reference method or clinical evidence, we recommend retesting:

- i) Samples from monitored patients to which lot 721101 has assigned unexpected higher values than the ones obtained for the same patient with previous lots.
- ii) Any first time sample reading above the reference range as defined by each laboratory.

Please ensure that no further testing is performed using the above mentioned lot. Please immediately destroy any remaining inventory of this lot you may have. Complete the bottom portion of this notification and return by fax or mail as explained below. DiaSorin will contact your laboratory to arrange collection of these kits and to supply replacement kits to perform the required retesting.

We apologize for any inconvenience this may cause you. For any further information you might need, please contact your DiaSorin representative

Best regards,

DiaSorin Quality Assurance
专专专者者中心,我们的自己的,我们的,我们的,我们的,我们的,我们的,我们的,我们的,我们的,我们的,我们

RETURN TO FAX NO: +39.0161.487.940
ATTN: QUALITY ASSURANCE

RETURN BY MAIL TO: DiaSorin
ATTN: QUALITY ASSURANCE
Via Crescentino snc
13040 Saluggia (VC) - Italy

(Please Print)

NAME:
INSTITUTION:
No. OF KITS REMAINING:

DATE:
SIGNATURE:

Product: LIAISON ® CEA Kit Part No. 314311 Kit Lot: 721101