BIOCARE MEDICAL

Biocare Medical
60 Berry Drive
Pacheco, CA 94553

Tel 800.799.9499
Fax 925.603.8080

Urgent Field Safety Notice

Commercial name of the affected product: Prostate Specific Antigen (PSA)
FSCA identifier (e.g. date): 03/27/2020
Type of action: Return of a Device

Date: 03/27/2020

Dear Biocare Medical Customer,

TABLE A: DETAILS ON AFFECTED DEVICE(S)

Part Number	Lot Number
VLTR390G20	032119
VLTR390G20	052819
CME390AK	032719

DESCRIPTION OF THE PROBLEM

Our record indicates that you purchased one of the Prostate Specific Antigen (PSA) devices listed in Table A between April 30, 2019 and October 11, 2019. According to the European IVDD Directive 98/79/EC, PSA falls under Annex II, List B of the Directive, for which it cannot be self-declared as CE IVD. Per Article 17, manufacturer is required to withdraw from the market when CE marking has been wrongly affixed. As a result, this Advisory Notice is published for market withdrawal due to mislabeling.

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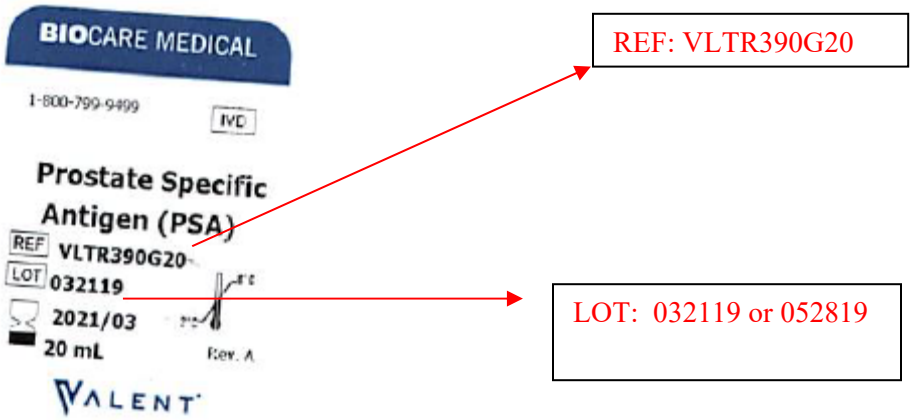
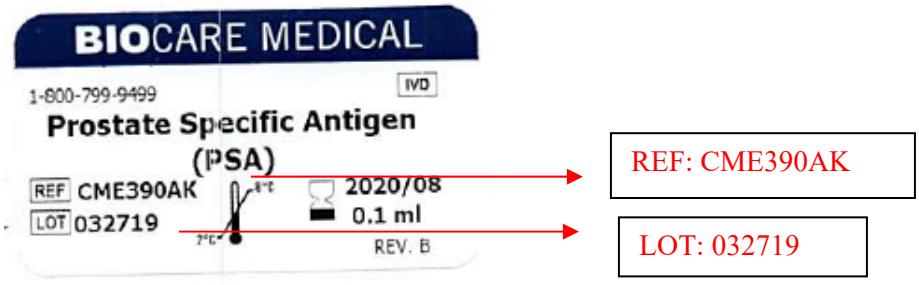
HOW TO IDENTIFY PRODUCT

Immediately inspect all **Prostate Specific Antigen (PSA)** in your possession, including partially used product, and identify product subject to Field Safety Notice (reference enclosed photographs as guide).

Photographs





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ACTIONS REQUIRED

1) Please immediately discontinue use and distribution of the identified affected lot numbers.
2) If you may have further distributed this product, please identify those customers and notify them at once of this Field Safety Notice. Your notification to your customers should include a copy of this notice.
3) Identified products shall be disposed of in accordance with applicable national, state, and local laws and regulations.
4) Complete attached Return Response Form and return to Biocare Medical by **April 24, 2020.**

PRODUCT REPLACEMENT

A product replacement with Research Use Only (RUO) labeled PSA is also sent concurrently with this Advisory Notice at no charge. The quantity of replacement is based on our record of your purchase history of the affected product lots.

CLINICAL SIGNIFICANCE

It is determined that the mislabeling would pose no risk to the patients since the devices were manufactured and tested according to the required specifications.

Biocare Medical appreciates your attention to this matter, and we apologize for any inconvenience this action may cause.

If you have any questions related to this Field Safety Notice, please don't hesitate to contact me.

Sincerely,
Johanna Saito

Johanna Saito | Regulatory Affairs Manager
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