CADENCE SCIENCE

7 July, 2015

URGENT FIELD SAFETY NOTICE

Perfectum Tuberculin Glass Syringe & Micro-Mate Tuberculin Glass Syringe

Part / Catalog #	Lot #	Packaged Lot #	Qty distributed	Distribution Country
5202	155195	79713-04	144	USA
5202	155195	79713-04	6	CANADA
5202	155287	80468-05	150	USA
5202	156510	W003542/1	144	USA
5202	156510	W003542/1	6	CANADA
5202	156829	W006324/1	150	USA
5205	154673	79748-03	420	USA
5208	155215	79895-01	388	USA
5208	155260	80044-02	12	DENMARK
5208	155761	82350-01	399	USA
5208	156839	W006510/1	400	USA
5209	153543	71880-01	48	USA
5209	154469	76434-01	50	USA
5209	154469	76434-01	50	THAILAND
5209	155203	79748-01	100	USA
5209	155261	80044-03	96	USA
5209	155261	80044-03	4	ITALY
5209	156271	W001711/1	36	USA
5209	156352	W002337/1	100	USA
5209	156418	W002886/1	86	USA
5209	156418	W002886/1	14	CANADA
5212	157023	W008136/1	120	USA
5212	157106	W008686/1	72	USA
5212	157369	W011240/1	2	USA
5212	157369	W010905/1	12	USA
5212	157369	W012315/1	3	USA
5212	157369	W014053/1	3	USA
5212	157369	W015838/1	3	USA
5212	157369	W011240/1	1	USA

Dear customer,

Cadence Science is initiating a field safety corrective action for the product listed on page one. This letter contains important information that needs your immediate attention.

ISSUE:
Cadence Science was notified by a customer that the graduation marks of the syringe are not centered with the numeric position marks on the syringe barrel. The potentially affected lots and products are listed in the table on page one.

IMPACT:
The misalignment of the graduation marks with the numeric position on the barrel may result in over or under dosing. The impact of this condition may vary depending on the use.

(1) Tuberculin testing use: the most common test is the Mantoux test and the usual dosing is 0.1ml in one application.
    a. Tuberculin testing use: under-dosing of tuberculin test may result a false-negative, this could potentially impact public health.
(2) Allergy testing:
    a. If syringes are being used to administer allergens for allergy testing, this could result in inaccurate test results and/or inaccurate dosing information included in the medication labeling.
(3) Other medication dosing when precise small doses are needed
    a. If the syringe is being used to measure other types of medication for administration, inaccurate test results and/or inaccurate dosing information could result and/or more severe issues could result depending on the type of medication being administered and the population (neonate, pediatric, adult).

ACTIONS TO BE TAKEN:
Cadence Science, Inc. is asking all customers to follow the steps below:

1. Recalled products must not be used.
2. Locate and remove all affected products from customer's facility.
3. Contact Cadence Science, Inc. using the Response Form provided to arrange the return and credit.
4. If this information is received by a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, then notify their customers of this action so that those customers can locate and remove all affected products.
5. If the syringe was utilized to develop test results, review applicable patient test results and notify other organizations to which incorrect test results may have been provided.

RESOLUTION:
Cadence Science is committed to providing quality products to our customers and we are taking appropriate internal corrective actions that will be reviewed by our Notified Body.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter and indicate this on the Response Form.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have specific questions regarding this notice, please contact Cadence Science, Inc.

Bob Trahan – Quality Manager	800-252-3371	RTrahan@cadenceinc.com
Jeff Crist – VP Quality & Regulatory	540-245-1022	Jeff@cadenceinc.com

We apologize for the inconvenience that this may have caused.

Sincerely,

Jeff Crist
Vice President Quality & Regulatory Affairs

Enclosure:
1) Label and product Identification guide
2) Customer Response form

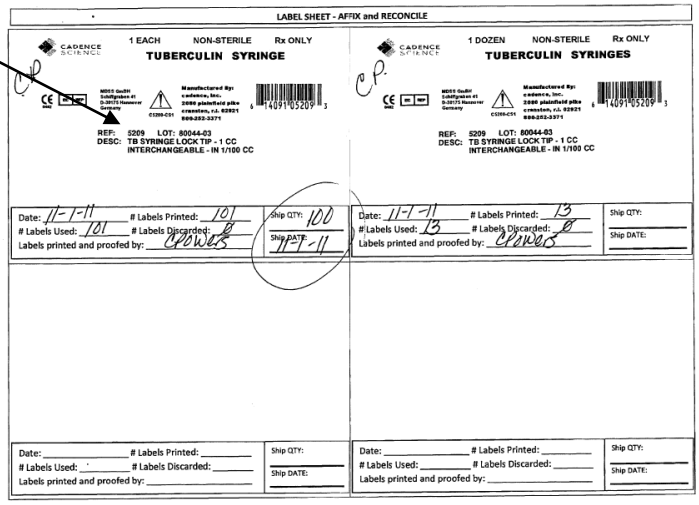
Cadence Science Ref: HHE 2015-1
MDSS ref.: MDD15.094

URGENT SAFETY FIELD NOTICE

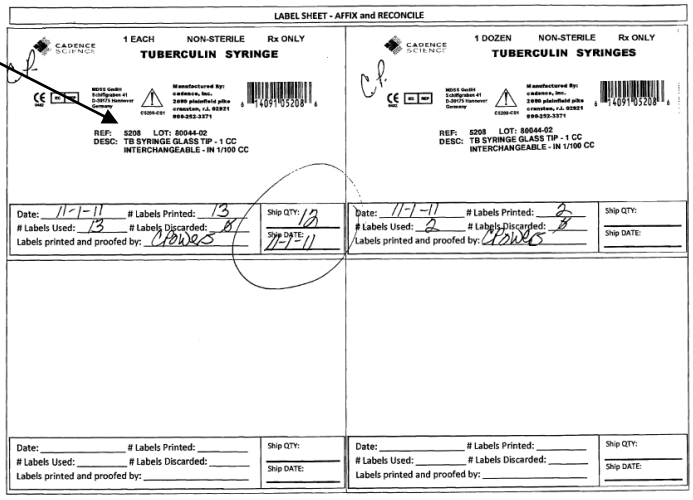
Product Identification

1) Labels:

5209 label

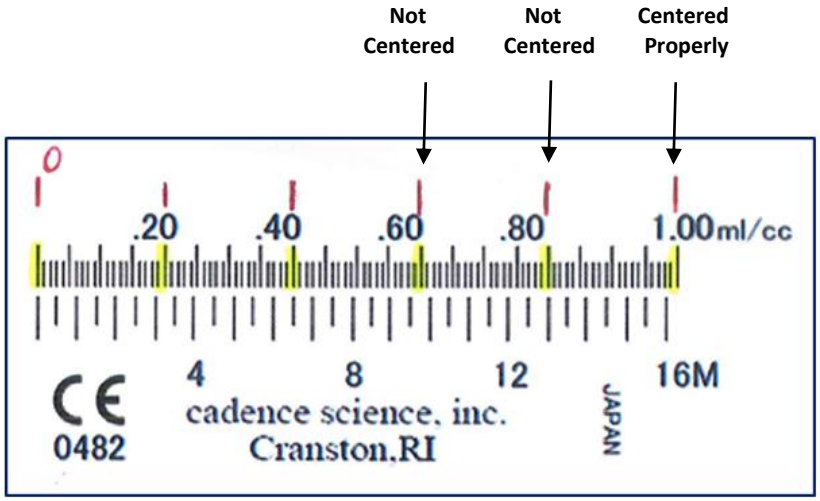


5208 label



2) **Product/Unit ID:**

a. **If the syringe has been removed from the outer packaging it can be identified by looking at the graduations on the syringe barrel. While the graduations marks are correct for volume, the numeric marks do not correctly align.**



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URGENT SAFETY FIELD NOTICE
Customer Response Form

Product: Perfectum Tuberculin Glass Syringe & Micro-Mate Tuberculin Glass Syringe.
Catalog numbers 5202, 5205, 5208, 5209, 5212

Lot numbers: All affected part numbers are listed below. Distribution of to EU is limited to parts 5208 and 5209.*

Action	Lot #	Qty	Date	Comments
Locate and Quarantine all products:				
Part # 5202				
Part # 5205				
(DENMARK)* Part # 5208				
(ITALY)* Part # 5209				
Part # 5212				

Please check the appropriate box (es) to describe your business

[ ] Wholesaler / distributor
[ ] Laboratory
[ ] other _____

Was the device utilized to provide test results? Yes / No
If yes, were other organizations notified per the actions required? Yes / No (provide details)

All inventory has been verified and affected products have been removed from use. Yes / No

Name:_____
Title: _____
Tel. number ( ) _____
e-mail address: _____
Firm Name: _____
Address: _____
City/State: _____

Please return to this completed form within 10 days.
To: FSN HHE2015-1@Cadeneinc.com
or
Cadence Science, Inc.
Attn: Quality Manager, FSN
2080 Plainfield Pike
Cranston, RI 02921
USA

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