NRC FORM 591M PART 1
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Roche Diagnostics Corporation Indianapolis, IN REPORT 205-001/	U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-34052	13-24532-02	Oct. 31, 2005

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection

☒ 1. Based on the inspection findings, no violations were identified.

☒ 2. Previous violation(s) closed.

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	**Deborah A. Piskura**	DAPiskura	10/31/05

NRC FORM 591M PART 3
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Roche Diagnostics Corporation REPORT NUMBER(S) **2005-001**	**Region III** **2443 Warrenville Road** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-34052	13-24532-02	Oct. 31, 2005

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126	03.01, 03.02, 03.03, 03.04, 03.05, 03.06, and 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02410	G2 5	Jeanne Steinfeld, RSO	317.352.1231

[X] Main Office Inspection — Next Inspection Date: Oct. 2010

[ ] Field Office _____

[ ] Temporary Job Site _____

PROGRAM SCOPE

This licensee was a large manufacturer of "cold" diagnostic kits, employing 3500 individuals at its Indianapolis Diagnostic Headquarters. The licensee was authorized to use CHIPS and Cr-51 for *in vitro* research and product development. Four individuals were authorized to use RAM.

This inspection consisted of a tour of the lab, the radioactive material and waste storage areas; review of selected records; interviews with licensee staff and observations of experiment set-ups.