

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Roche Diagnostics Corporation
Indianapolis, IN
REPORT 205-001

2. NRC REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)

030-34052

4. LICENSEE NUMBER(S)

13-24532-02

5. DATE(S) OF INSPECTION

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	<i>Deborah A. Piskura</i>	10/31/05

(10-2003)
10 CFR 2.201**Docket File Information**
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Roche Diagnostics Corporation REPORT NUMBER(S) 2005-001		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-34052	4. LICENSE NUMBER(S) 13-24532-02	5. DATE(S) OF INSPECTION Oct. 31, 2005	
6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, and 03.07		
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 02410	2. PRIORITY G2 5	3. LICENSEE CONTACT Jeanne Steinfeld, RSO	4. TELEPHONE NUMBER 317.352.1231
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: Oct. 2010	
<input type="checkbox"/> Field Office _____			
<input type="checkbox"/> 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.