

DEVICE LISTING

Complete and Return to:

Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
2098 Gaither Road
Rockville, MD 20850

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER A 973343	2. REASON FOR SUBMISSION <input checked="" type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing	3. REPORT DATE			4. OWNER / OPERATOR ID NUMBER 9026669
		MO.	DAY	YR.	
		03	11	1999	

5. OWNER / OPERATOR NAME
SIERRA DIAGNOSTICS, INC.

6. ADDRESS (Check if same as submitted on FDA Form 2891)
a. NUMBER and STREET
21109 LONGEWAY ROAD #C

b. CITY, STATE, ZIP CODE
SONORA, CA 95370

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME
GENERAL PURPOSE REAGENT

8. CLASSIFICATION NUMBER
LDT

9. PROPRIETARY NAME (Brand Name)
DNA/RNA PROTECT

QUA/RNA PROT

10. COMMON OR USUAL NAME
NUCLEIC ACID PRESERVATIVE

11. FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS

a. NAME

b. REGISTRATION NUMBER

REGISTRATION NO.	ESTABLISHMENT NAME AND ADDRESS <small>(Identification of Sites Where Listed Device is Produced) (Name, Street Number, City, State or Country, ZIP or Postal Code)</small>	ESTABLISHMENT TYPE				
		M	R	S	T	X
A 2953142	Sierra Diagnostics, Inc. 21109 Longeway Road #C Sonora, CA 95370	x				
B						
C						
D						

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address.

13. SIGNATURE

14. TYPED OR PRINTED NAME
Tony K. BAKER