

MATERIALS LICENSE

Amendment No. 07

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

OFFICIAL RECORD COPY

Licensee	In accordance with letter dated July 23, 1996.	
1. Chiron Diagnostics Corporation	3. License Number 20-12960-04G is amended in its entirety to read as follows:	
2. 333 Coney Street East Walpole, Massachusetts 02032-1597	4. Expiration Date November 30, 2001	
	5. Docket or Reference No. 030-10907	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Iodine 125	A. Prepackaged in vitro kits	A. Not applicable
9. Authorized use		
A. Pursuant to Section 32.71 of 10 CFR Part 32, the licensee is authorized to distribute in vitro kits to persons generally licensed pursuant to Section 31.11 of 10 CFR Part 31, or equivalent provisions of the regulations of any Agreement State.		

CONDITIONS

10. The licensee is authorized to distribute prepackaged in vitro kits from facilities located at 333 Coney Street, East Walpole, Massachusetts.
11. The license does not authorize possession or use of licensed material.
12. Any proposed changes in packaging, labeling, shielding or instructions for use and storage shall be submitted to the Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and approval of the changes shall be received by the licensee prior to implementing the changes.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

20-12960-04G

Docket or Reference Number

030-10907

Amendment No. 07

(Continued)

CONDITIONS

13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated October 23, 1990
- B. Letter dated October 1, 1991
- C. Letter dated July 23, 1996

Date

OCT 25 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

John R. McGrath

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

OCT 25 1996

Maureen T. Gillis
Radiation Safety Officer
Chiron Diagnostics Corporation
333 Coney Street
East Walpole, Massachusetts 02032-1597

Dear Ms. Gillis:

This refers to your license amendment request. Enclosed with this letter are the amended licenses. Please note that as part of these amendments, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration dates of your licenses have been extended by a period of five years. The new expiration date is stated in Item 4 of each license.

Please review the enclosed documents carefully and be sure that you understand and fully implement all the conditions incorporated into the amended licenses. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
John R. McGrath

John R. McGrath
Senior Health Physicist
Division of Nuclear Materials Safety

License Nos. 20-12960-02
 20-12960-04G
Docket Nos. 030-09001
 030-10907
Control Nos. 123491
 123492

Enclosures:
Amendment No. 23
Amendment No. 07

OFFICIAL RECORD COPY

ML 10

DOCUMENT NAME: R:\WPS\MLTR\L2012960.02

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	McGrath <i>gall</i>						
DATE	09/24/96		09/ /96		09/ /96		09/ /96

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CIBA-CORNING

* Ciba Corning Diagnostics Corp.
333 Coney Street
East Walpole, Massachusetts 02032-1597
Telephone 508-668-5000
Fax 508-668-4591

July 23, 1996

030-10907

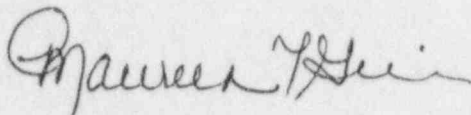
Licensing Assistant Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

To Whom It May Concern,

Please see the attached two amendment applications for NRC license numbers 20-12960-02 and 20-12960-04G. Enclosed is one check for the administrative fees.

Thank you.

Sincerely,



Maureen T. Gillis
Radiation Safety Officer

OFFICIAL RECORD COPY

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JUL 25 1996

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 20-12960-04G
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Ciba Corning Diagnostics Corp.
333 Coney Street
East Walpole, MA 02032

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same as 2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Maureen T. Gillis

TELEPHONE NUMBER

508-660-4207

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3K</u> AMOUNT ENCLOSED \$ <u>310.00</u>
13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION	

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE Manufacturing
William A. Sartorelli, Exec. Dir. Operations

SIGNATURE

William G. Sartorelli

DATE

7/24/96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

123492JUL 25 1996

Information Needed for Change of Ownership Application
(Re: IN 89-25, Rev. 1)

The applicant should provide the following information concerning changes of ownership or control by the applicant (transferor and/or transferee, as appropriate):

1. The new name of the licensed organization. If there is no change the licensee should state so.

Chiron Diagnostics Corporation - to be effective November 1, 1996.

2. The new licensee contact and telephone number(s) to facilitate communications.

The license contact will remain the same, i.e. Maureen T. Gillis, Radiation Safety Officer at (508) 660-4207.

3. Any changes in personnel having control over licensed activities (i.e. officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.

No changes in personnel having control over licensed activities will occur.

4. An indication of whether the transferor will remain in non-licensed business without the license.

Not applicable.

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and changes of ownership.

Chiron Diagnostics Corporation is a wholly owned subsidiary of Chiron Corporation, 4560 Horton Street, Emeryville, CA 94608-2916. (The actual name change will occur on November 1, 1996.)

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e. changes in operating or emergency procedures).

No changes in organization, location, facility, equipment, or procedures are planned

7. A detailed description of any changes in the use, possession, location or storage of the licensed materials.

No changes in the use, possession, location, or storage of licensed materials are planned.

8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.

Please be advised that we have made obsolete several generally licensed products. We wish to continue to sell the following products:

PRODUCT NAME	CATALOG NUMBER
Magic T3 Component Set	472341
Magic 1-FT4 Component Set	472344
Magic Ferritin Component Set	472347
Magic B12/Folate Component Set	472345
Magic Cortisol Component Set	472362
Magic Mab TSH Combo	472385
Magic No Boil Kit	472352
Magic Digoxin Component Set	472346
Magic T4 Component Set	472340
Magic T3 Uptake Component Set	472342
Magic 1-FT3 Component Set	472375

For your convenience, we have attached the current product labeling and accompanying package insert with our current corporate name and address. Discussions with Richard Gibson on 9/13/95 indicated that we could continue to use our current labeling and inserts for a grace period of up to one full year following our name change. On Mr. Gibson advice, we will be submitting a second amendment with the actual labels and inserts showing our new corporate name and address. (Please note at that time our corporate address listed on the product labeling and inserts will match the location of manufacture as permitted by our NRC license 20-12960-02.)

9. An indication of whether all surveillance items and records (i.e. calibrations, leak tests, surveys, inventories and accountability requirements) will be current at the time of transfer. A description of the status of all surveillance requirements and records should also be provided.

All surveillance items required by the current license are up to date.

10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d), public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license termination's.

All records concerning the public dose, waste disposal by release to sewers, incineration, radioactive materials spills will continue as currently performed (i.e. will be maintained by Chiron Diagnostics Corporation.)

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

As the licensed use of radioactive material is still planned decontamination will not occur. Chiron Diagnostics Corporation agrees to assume responsibility for decontamination at the facility.

12. A description any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36 and 70.25. This should include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup at the time of transfer.

Given that our possession limits are less than the thresholds, decontamination plans are not required by regulation.

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 20 CFR 30.35(g), implementing decontamination activities and decommissioning of the site, and completing corrective actions for open inspection items and enforcement actions.

Chiron Diagnostics Corporation agrees to abide by all license conditions.

With regard to contamination of facilities and equipment, the transferee should confirm in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to before change of control or ownership.

See item 11.

With regard to open inspection items, etc. the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions, or the transferee proposes alternative measures for meeting the requirements, or the transferor provided a commitment to close out all such actions with NRC before license transfer.

There are no open inspection items.

14. Documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

See item 13.

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its programs, to ensure compliance with the license and regulations.

Chiron Diagnostics Corporation agrees to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license.

OVERSIZE ATTACHMENTS AVAILABLE
IN REGION I

BETWEEN:

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: PROGRAM CODE: 03244
: STATUS CODE: 0
: FEE CATEGORY: 3K
: EXP. DATE: 20011130
: FEE COMMENTS: -----
: DECOM FIN ASSUR REQD: N

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A. REGION

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Log Aug 4
Remitter
Check No. 60011608
Amount \$890 \$310 Remainder
Pay To Order 3K
Type of Fee AMD
Date Check Recd 8/4/94
Date Completed
By. BS

applies to control
123491

(Also see
12349.)