

### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

March 18, 2015

Biochem Diagnostics Laboratory, Inc ATTN: Teo Gherasim 18161 W.13 Mole Rd. – D3 Southfield, MI 48076

# SUBJECT: GENERAL LICENSE REGISTRATION CERTIFICATE FOR in vitro TESTING

Dear Mr. Gherasim:

This letter is to confirm that we have received the completed U.S. Nuclear Regulatory Commission (NRC) form 483, "Registration Certificate—*in vitro* Testing with Byproduct Material Under General License." In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 31.11, "General license for use of byproduct material for certain *in vitro* clinical or laboratory testing," the possession, use, or transfer of byproduct material under this part is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and has received from the NRC a validated copy of NRC Form 483 with a registration number assigned; or has a license that authorizes the medical use of byproduct material that was issued under 10 CFR Part 35.

The NRC reviewed your Registration Certificate (NRC form 483) and assigned a registration number **GL-727093**. Please note that no further action is required from you at this time. If you change any information included in the enclosed Registration Certificate, you must notify the NRC in writing within 30 days after the effective date of such change.

You may refer to 10 CFR 31.11 for additional regulatory requirements that you must meet as a general licensee. If you have any questions regarding your registration or your responsibilities as a General Licensee please call me at (301) 415-6004 or visit www.nrc.gov/materials/medical.html.

You may submit your correspondence referencing the registration number to:

Director, Office of Nuclear Material Safety and Safeguards ATTN: GLTS U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

Sincerely,

IRAI Hector Rodriguez-Luccioni Materials Safety Licensing Branch Division of Material Safety, States, Tribal, and Rulemaking Programs Office of Nuclear Material Safety and Safeguards Biochem Diagnostics Laboratory, Inc ATTN: Teo Gherasim 18161 W.13 Mole Rd. – D3 Southfield, MI 48076

# SUBJECT: GENERAL LICENSE REGISTRATION CERTIFICATE FOR in vitro TESTING

Dear Mr. Gherasim:

This letter is to confirm that we have received the completed U.S. Nuclear Regulatory Commission (NRC) form 483, "Registration Certificate—*in vitro* Testing with Byproduct Material Under General License." In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 31.11, "General license for use of byproduct material for certain *in vitro* clinical or laboratory testing," the possession, use, or transfer of byproduct material under this part is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and has received from the NRC a validated copy of NRC Form 483 with a registration number assigned; or has a license that authorizes the medical use of byproduct material that was issued under 10 CFR Part 35.

The NRC reviewed your Registration Certificate (NRC form 483) and assigned a registration number **GL-727093.** Please note that no further action is required from you at this time. If you change any information included in the enclosed Registration Certificate, you must notify the NRC in writing within 30 days after the effective date of such change.

You may refer to 10 CFR 31.11 for additional regulatory requirements that you must meet as a general licensee. If you have any questions regarding your registration or your responsibilities as a General Licensee please call me at (301) 415-6004 or visit www.nrc.gov/materials/medical.html.

You may submit your correspondence referencing the registration number to:

Director, Office of Nuclear Material Safety and Safeguards ATTN: GLTS U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

> Sincerely, /RA/ Hector Rodriguez-Luccioni Materials Safety Licensing Branch Division of Material Safety, States, Tribal, and Rulemaking Programs Office of Nuclear Material Safety and Safeguards

Enclosure: NRC Form 483 - GL727093

DISTRIBUTION: RIII/DNMS

## ADAMS Accession Nos.: ML15077A345 (letter) ML15077A307 (in-vitro form)

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Hector Rodriguez-Luccioni	Hipolito Gonzalez	Hector Rodriguez-Luccioni
DATE	03/18/2015	03/18/2015	03/18/2015

## OFFICIAL RECORD COPY