

Any Imaging Center Surveys Filed by Hospital

**U.S. Department of Health and Human Services
Food and Drug Administration**

CERTIFIED MAMMOGRAPHY FACILITY

This certifies that

Jasper Health Services

has complied with the requirements of the Mammography Quality Standards Act of 1992 and is hereby authorized to perform mammography examinations, pursuant to 42 U.S.C. 263b.

Facility ID Number: 245217

Expiration Date: January 2, 2023

Patients may report comments/complaints to:

*Mammography Accreditation Program
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191-4397*

Scott Gottlieb, MD

Scott Gottlieb, M.D.
Commissioner of Food and Drugs



Helen J. Barr, MD

Helen J. Barr, M.D.
Director
Division of Mammography Quality Standards
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health



American College of Radiology

Mammographic Imaging Services of

Jasper Health Services

898 College St
MONTICELLO, Georgia 31064

were surveyed by the
Committee on Mammography Accreditation of the
Commission on Quality and Safety

The following unit was approved

**General Electric Co. (GE Medical Systems) SENOGRAPHIE
PRISTINA 2019 DBT**

Accredited from:

January 02, 2020 through January 02, 2023

Don M. Lloyd, MD

Debra J. Montross, MD, FRCR

CHAIRMAN, COMMITTEE ON
MAMMOGRAPHY ACCREDITATION

PRESIDENT, AMERICAN COLLEGE OF
RADIOLOGY



First Class Mail

January 3, 2020

FDA MQSA Facility ID#245217
Laurence A Steinfeld
Jasper Health Services
898 College St
MONTICELLO, GA 31064

Dear Dr. Steinfeld:

The Food and Drug Administration (FDA) has determined that your facility meets the requirements for certification under the Mammography Quality Standards Act of 1992 (MQSA) as amended by subsequent Mammography Quality Standards Reauthorization Acts (MQSRA). The enclosed MQSA certificate certifies your facility as a lawful provider of mammography services until the expiration date on the certificate or in the event of certificate suspension or revocation. If your accreditation body (AB) subsequently denies accreditation, FDA will notify you regarding your status as a certified facility. You may dispose of or file any MQSA certificate previously held by your facility.

MQSA certification authorizes a facility to lawfully perform mammography including: operation of x-ray equipment to produce mammograms; processing of films; interpretation of mammograms; medical record keeping; reporting and patient notification; and outcomes data collection.

Furthermore, as a certified mammography facility, you must:

- uphold the requirements of the MQSA;
- obtain and/or maintain facility accreditation with an FDA-approved AB (e.g., the American College of Radiology or the States of Arkansas, Iowa and Texas) and notify them of status changes (e.g., additions or changes in equipment or personnel, facility mailing or physical address, facility location, official contacts or services provided);
- prominently display the facility's MQSA certificate in view of mammography patients;
- undergo annual MQSA inspections and re-inspections (if necessary); and,
- pay associated MQSA inspection fees, when billed by FDA.

You must cease performing mammography services immediately and no longer display the certificate if the certificate expires or is suspended or revoked. If you wish to resume offering mammography services, you must contact your FDA-approved AB or, in the

case of suspension or revocation, the FDA to pursue your facility's options. If your accreditation body (AB) subsequently denies accreditation, FDA will notify you regarding your status as a certified facility.

If FDA determines that your facility at any time performed mammography without a valid certificate, you could be subject to sanctions under MQSA. These sanctions include

- civil money penalties of up to \$11,000 per violation per day for performing mammography without a valid certificate (42 U.S.C. 263b(h)(3)),
- suspension or revocation of certification (42 U.S.C. 263b(i)), and;
- injunction proceedings by FDA against your facility (42 U.S.C. 263b(j)).

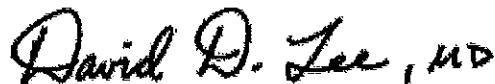
Also, without a valid certificate, reimbursement ceases for diagnostic or screening mammography services from the Centers for Medicare and Medicaid Services (CMS).

Please access our MQSA Website @ <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm> (search on the topic) to obtain information regarding the certification process, inspections and inspection fees, or general MQSA information.

Direct questions about this certificate to our MQSA Hotline via one of the options provided below

MQSA Hotline Phone Number:	1-800-838-7715
MQSA Fax Number:	Food and Drug Administration 1-443-285-0689
MQSA Hotline Email Address:	MQSAHotline@versatechinc.com
MQSA Hotline Mail Address:	Mammography Quality Assurance Program Food and Drug Administration P.O. Box 6057 Columbia, MD 21045

Sincerely yours,



David D. Lee, MD
Director
Division of Mammography Quality Standards
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
MQSA Certificate