Declaration of Conformity for IVDs

IVDD Category (check one): Annex II [ ] Self-declared [X]

Legal Manufacturer's Name: Abbott Molecular Inc.

Legal Manufacturer's Address: 1300 East Touhy Ave., Des Plaines, IL 60018

Name of Authorized Representative in Europe: ABBOTT GmbH & Co. KG, Delkenheim

Address of Authorized Representative in Europe: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

Approval Certificate No.: N/A

List Number(s) of Device	Name(s) and Description(s) of Device
9K12-01	Abbott multi-Collect Specimen Collection Kit

GDMN Code N/A

Notified Body's Company affiliation(if involved): N/A

Notified Body's Address (if involved): N/A

Notified Body's Number (if involved): N/A

Name of technical documentation owner: Abbott Molecular Inc.

Address of technical documentation owner: 1300 East Touhy Ave., Des Plaines, IL 60018

EC Authorized Representative's Name: ABBOTT GmbH & Co. KG, Delkenheim

EC Authorized Representative's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

I, the undersigned, hereby declare that the *in vitro* diagnostic medical device(s) described above and bearing the CE-Marking, conform with the applicable provisions of Medizinproduktegesetz (German Medical Devices Act) transposing EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Paula E Martin

Full Name (printed): Paula E. Martin

Position: Regulatory Section Manager

Date: January 23, 2006

Place: Abbott Molecular Inc., Des Plaines, IL 60018

Date Issued: January 23, 2006

Supersedes: N/A