



## PRESS RELEASE

### Hutman Diagnostics AG, Receives EN ISO 13485:2012 Certification

Basel, March 2<sup>nd</sup>, 2015

Hutman Diagnostics AG is proud to announce that on February 20<sup>th</sup>, 2015 the company was successfully certified as EN ISO 13485:2012 + AC: 2012 and ISO 13485:2003 compliant, covering the following activities:

“ Design and development of molecular biology-based kits and related systems for *in vitro* diagnostics.”

The certification is accredited by the Tüv Süd Product Service GmbH in Germany.

To achieve certification, Hutman Diagnostics AG had to pass an intense evaluation process including the entire development, editing and implementation of the quality management system, pre-audit, 1<sup>st</sup> stage documentation audit, 2<sup>nd</sup> stage certification audit and clearance of identified minor nonconformities by implementation of corrective actions.

ISO 13485:2003 is an international standard presenting the requirements for a quality management system for the design and manufacture of medical devices and *in vitro* diagnostic devices. It is based on principles that have proven to strengthen customer focus and improve management, internal processes and external relationships, thus enhancing the global organization's performance. EN ISO 13485:2012 + AC:2012 is harmonized with respect to the European medical devices directives and provides guidance to develop and provide medical devices and related services that consistently meet product, regulatory and statutory requirements for the European market. Implementation of a quality management system is a requirement towards obtaining CE mark, the regulatory clearance requirement recognized in Europe and other countries.

Hutman Diagnostics is an *in vitro* diagnostics product development company with a unique technology platform that can rapidly detect pathogen involvement from a variety of uncultured specimens. For more information please visit our webpage at [www.hutmandiagnostics.com](http://www.hutmandiagnostics.com) or contact Mr. Paul R. Hofer, CEO | CFO.

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