

# Competency Statement

## Genome Diagnostics, Department of Human Genetics, RadboudUMC

The undersigned, the head of the Genome Diagnostics division of the Department of Human Genetics at the RadboudUMC states in relation to the competence of the department to perform diagnostic tests, analyze data, interpret and report the results that:

- The laboratory is accredited by the Dutch Accreditation Council in accordance with the ISO15189\_2012 under number M100. Certificate on the website.
- All diagnostic procedures (and subsequent results) listed in the scope and operations list are included under this ISO15189\_2012 accreditation
- Changes in the performance of a diagnostic test which are important for the referring clinician will be clearly communicated.
- Doubts about the reliability and / or corrections to results will be communicated immediately to the relevant referring clinician(s).
- The laboratory participates in quality assessment schemes for the available tests, within the discipline generally accepted organizations. Certificates of participation are on the website.
- If, for a diagnostic test no quality assessment test is available by one of the EQA's, the laboratory will start an alternative manner of assessment to determine the validity of the test methodology for the described application.
- Determining the appropriateness of the method is carried out by, or under the supervision of a Clinical laboratory geneticist recognized by the VKGL (Dutch Association for Clinical Genetics Laboratories) .
- All results are authorized by a certified Clinical Laboratory Geneticist.
- The laboratory and associated specialists are regularly visited by the review committee of the VKGL.
- The RadboudUMC acts in accordance with the privacy policy that has been established in the General Data Protection Regulation (GDPR) and the Dutch Medical Treatment Act (WGBO). This implicates that every person within the RadboudUMC abides by the privacy policies to ensure that patient information is only available to relevant professionals.

H. G. Yntema, PhD

Head Genome Diagnostics Laboratory, Department Human Genetics, RadboudUMC

