# 2nd International Workshop on Klinefelter Syndrome

## March 10–12, 2016
## Münster, Germany

### Venue

Factory Hotel

An der Germania Brauerei 5
48159 Münster, Germany

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Alberto Ferlin
Italy

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Joana Viana
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Joachim Wistuba
Germany

Michael Zitzmann
Germany

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## Will steroid measurements affect the outcomes of clinical trials? Comparison between immunoassay and mass spectrometry in men with Klinefelter Syndrome undergoing human chorionic gonadotropin stimulation test

D. Santi [1,2] L. Roli [3] S. Belli [1], S. Tagliavini [3] S. Cavalieri [4] MC. De Santis [3] E. Baraldi [3] F Fanelli [5] M. Mezzullo [5] A.R. Granata [2] U. Pagotto [5] R. Pasquali [5] V Rochira [1,2] C. Carani [1] T Trenti [3] M. Simoni [1,2,6]

[1] Unit of Endocrinology Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Italy [2] Department of Medicine, Endocrinology Metabolism and Geriatrics, Azienda USL of Modena, Italy [3] Department of Laboratory Medicine and Pathological Anatomy Azienda USL of Modena, Italy [4] Laboratory of clinical and endocrinological analysis, Arcispedale S. Maria Nuova, Reggio Emilia, Italy [5] Endocrinology Unit, Department of Medical and Surgical Sciences, Centre for Applied Biomedical Research, Unit S. Orsola-Malpighi Hospital, Alma Mater University of Bologna, 40138 Bologna, Italy [6] Center for Genomic Research, University of Modena and Reggio Emilia, Italy

Liquid-chromatography tandem mass-spectrometry (LC-MS/MS) was developed in parallel to Immunoassays (IA) and represents the gold standard for steroid assays. Recently our group has demonstrated that in men with Klinefelter Syndrome (KS) Leydig cells respond to human chorionic gonadotropin (hCG) stimulation, even if the testosterone (T) production is impaired, using only LC-MS/MS. To compare IA and LC-MS/MS performance, evaluating steroidogenesis after hCG stimulation in men with KS compared to control volunteers. Longitudinal, prospective, case-control clinical trial, in which 14 KS patients (36±9 years) not receiving T replacement therapy and 13 eugonadic control men (32±8 years) were enrolled. Serum steroids were evaluated at baseline and for 5 days after intramuscular injection of 5000 IU hCG using both routinely IA (chemiluminescent microparticle immunoassay radioimmunoassay and competitive immunoenzimatic assay) and LC-MS/MS. Progesterone (P), 17-Hydroxy-Progesterone (17OHP), androstenedione (A), T and estradiol (E2) were significantly higher using IA compared to LC-MS/MS ($p<0.001$ $p=0.043$, $p<0.001$ $p<0.001$ and $p<0.001$ respectively). IA and LC-MS/MS showed a direct correlation for 17OHP and T measurement ($r=0.850$, and $r=0.979$, respectively), and a moderate concordance ($\rho=0.844$ and $\rho=0.894$). A linear relationship was not excluded for T measurement ($p=0.590$) in spite of significant proportional and systematic errors. On the contrary a poor correlation ($r= 0.826$, $p<0.001$) with a poor strength ($\rho c=0.347$) of the agreement between the 2 methodologies was evident for A measurement. On the other hand, the two methodologies found the same significant 17OHP and T increasing-profile, although smoothed with IA. A linear regression between IA and LC-MS/MS performances is pointed out, although IA seems to be less specific than LC-MS/MS, with an overestimation trend of sex steroids levels. Moreover IA sensitivity seems to be poor when a slight hormonal change has to be detected, such as after hCG stimulation.