Results: 14 studies were found that compared the RS assay with BCI (1), BCI, EPclin, and ROR (1), EP/EPclin (2), MMP (6), and ROR (4). Overall discordance in risk stratification ranged from 43% to 66% between assays (Table). The RS assay classifies 12% of pts as high risk, compared with EP (63%), EPclin (48%), and MMP (46%), assays with low/high risk groups, and compared with BCI (16%) and ROR (33%), assays that, like the RS assay, use three risk groups.

Conclusions: The five most common genomic assays in clinical use for EBC risk-stratify pts differently and thus are not interchangeable. Of these, the RS assay classifies the smallest proportion of pts as high risk.

Legal entity responsible for the study: Zsuzsanna Varga

Funding: Genomic Health

Disclosure: Z. Varga: Consultant/advisor: Genomic Health, Roche. P. Sinn: Advisor: Genomic Health. D. McCullough, A. Lau, M.C. Stöppler, F.L. Baehner, C. Chao: Employment and stock ownership: Genomic Health. A. Seidman: Consultant/speaker: Genomic Health.

187P Summary of head-to-head comparisons of patient (pt) risk classifications by the 21-gene recurrence score (RS) assay and other genomic assays for early breast cancer (EBC)

Z. Varga[1], P. Sinn[2], D. McCullough[3], A. Lau[3], M.C. Stöppler[3], F.L. Baehner[3], C. Chao[3], A. Seidman[4]

[1]Departement Pathologie und Molekularpathologie, Universitätsspital Zürich, Zurich, Switzerland, [2]Sektionsleiter Gynäkopathologie, Pathologisches Institut, Heidelberg, Germany, [3]Medical Affairs, Genomic Health, Inc., Redwood City, CA, USA, [4]Department of Medical Oncology, Memorial Sloan-Kettering Cancer Center, New York, NY, USA

Background: Many genomic assays that assess recurrence risk in EBC are prognostic, but they differ in risk group stratification, which can affect clinical utility. Prospective outcomes of > 50K pts treated based on 21-gene RS results have shown that pts with low RS EBC can safely forgo chemotherapy. Because of its extensive validation and wide clinical use, the RS assay is a common comparator in head-to-head studies with other assays.

Methods: Published/presented studies of the RS assay performed on same tumor samples with Breast Cancer Index (BCI), EndoPredict (EP) or EP+clinical features (EPclin), MammaPrint (MMP), and/or Prosigna (ROR) assays were reviewed. Study findings were summarized descriptively.

Table: 187P

Discordance[a] Between the RS Assay and Other Assays

	BCI			ROR			EP/EPclin			MMP		
Study[b]	1-level	2-level	Overall	1-level	2-level	Overall	1-level	2-level	Overall	1-level	2-level	Overall
Sestak 2016	37%	5%	42%									
Bartlett 2016[c]				40%	10%	50%						
Alvarado 2015				37%	10%	46%						
Dowsett 2013				41%	3%	43%						
Sinn 2017				45%	20%	66%						
Varga 2013							29%/29%	18%/21%	47%/50%			
Clough 2013										38%	19%	57%
Denduluri 2011										34%	25%	58%
Maroun 2015										31%	22%	53%
Shivers 2013										26%	19%	44%

a. Overall=any discordance in risk classification between the RS assay and other; 1-level=discordance of one risk category (low ↔ intermediate or intermediate ↔ high); 2-level=discordance of two risk categories (low ↔ high). b. Four studies lacked risk classification information appropriate for inclusion in this table. c. Study used nonstandard RS cutoffs for the RS vs. MMP comparison.