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New Trends, Applications, and IVD Industry Analysis

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Emerging Tests: New Study Supports Feasibility of At-Home Urine Prostate Cancer Testing

One of the most challenging aspects of prostate cancer diagnosis is collecting urine samples from patients. In addition to being highly uncomfortable, post-digital rectal examination collection yields less than suboptimal samples. However, a new study suggests that the samples patients collect themselves at home may be at least equally reliable as current collection methods, not to mention a lot easier and more pleasant.

The Diagnostic Challenge

Measuring biomarkers contained in urine is the basis for diagnosing prostate cancer. Historically, a doctor collects a urine sample from the patient after performing a digital rectal examination of the prostate. The timing is important because the digital examination boosts the levels of prostatic secretion in the

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Genetic Testing: Proposed New Medicare Coverage Rules for NGS Germline Testing of Early-Stage Cancer Patients

Medicare coverage of germline next-generation sequencing (NGS) panels for early-stage cancer patient has been a topic of controversy of late. The problem began when the Centers for Medicare and Medicaid Services (CMS) instructed its Medicare Administrative Contractors (MACs) to impose new coverage restrictions on early-stage cancer testing. But after a public outcry, the agency seems to have backed off. Or has it?

The NGS Tests at Issue

NGS technology enables laboratory testers to read the order of nucleotide molecules on DNA and more effectively provides detailed information on multiple types of genetic alternations simultaneously. The NGS

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New Study Supports Feasibility of At-Home Urine Prostate Cancer Testing, *from page 1*

urine. However, research shows that the first urination of the day provides the highest and most consistent levels of biomarkers. The problem, of course, is that doctors rarely have access to that first-of-the-day urine. And home collection is unreliable and subject to sample spoilage and contamination.

The New Test

Researchers from the University of East Anglia (UAE) in the UK have pioneered a new test that enables detection of prostate cancer using urine samples that patients collect at home. The study, which was published in the published in the journal *BioTechniques* on Nov 29, 2019, demonstrates the effectiveness of a test called PUR (Prostate Urine Risk) in diagnosing aggressive prostate cancer and predicting whether patients will require treatment up to five years earlier than standard clinical methods.

But perhaps PUR's greatest benefit is that it can be performed on urine samples collected at home. The PUR test uses a commercial preservative allowing samples to be maintained at room temperature without loss of RNA quality.

The Study

The research team provided 14 participants with an At Home Collection Kit, and instructions to collect urine samples after waking up in the morning. They then compared the results of their home urine samples with samples collected after a digital rectal examination.

Each sample was centrifuged at 2500 ×g for 5 minutes. Supernatant was filtered through a 0.8-mm filter, and the cell pellet was stored in 1 ml phosphate-buffered saline at -80°C. The researchers used the Qiagen RNeasy kit to extract RNA from the cell sediment. They then extracted cfRNA from urine supernatant via microfiltration (MicroF) or high-volume vacuum extraction (HiVE). They assessed RNA quantity using a Qubit 2.0 Fluorometer and Qubit RNA HS Assay. They then used a Bioanalyzer 2100 and the RNA 6000 Pico kit to assess RNA quality and an Agilent sRNA kit to measure sRNA yield.

Based on comparisons between digital rectal examination (DRE) and non-DRE urine RNA yields and RT-PCR expression levels, the researchers concluded that the collection of non-DRE urine by men at home was a viable and simple option. The research team found that the urine samples taken at home showed the biomarkers for prostate cancer much more clearly than after a rectal examination. And feedback from the participants showed that the at home test was preferable.

Takeaway: The researchers say they intend to use the PUR methodology and at-home collection protocol to develop a testing kit for aggressive prostate cancer within the next 10 years. "Being able to simply provide

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*a urine sample at home and post a sample off for analysis could really revolutionize diagnosis," notes lead researcher **Dr. Jeremy Clark**, from University of East Anglia's Norwich Medical School. "It means that men would not have to undergo a digital rectal examination, so it would be much less stressful and should result in a lot more patients being tested."*

FDA WATCH

A roundup of recent cases and enforcement actions involving the diagnostics industry

Agency Targets Sale of IVD Reagents without Premarket Approval

Distribution of diagnostics and devices without premarket approval has featured prominently on the FDA's enforcement priority list this year. The agency has issued seven warning letters related to premarket approval in 2019 after issuing just one such warning letter in all of 2018.

Carolina Liquid Chemistries was on the receiving end of the most recently announced warning letter, which contends that the Greensboro-based firm sold Class I and II in vitro diagnostic (IVD) reagents without obtaining the necessary premarket approval. More specifically, Carolina Liquid failed to produce evidence showing that distributions of Tapentadol, Zolpidem, Spice and Fentanyl reagents branded only for forensic or research and development were restricted to appropriate research centers, law enforcement agencies or court mandated testing centers. The agency suspects that the reagents might have also been sold to pain management centers and a clinical testing laboratory for unapproved clinical testing applications. The FDA raised concerns about the sales history of Carolina Liquid reagents branded as for forensic and research use while inspecting the company's facilities last year.

New FDA Approvals

Here's a look at all the important new product approvals announced from mid-November through late December:

Manufacturer(s)	Product(s)
Ortho Clinical Diagnostics	Clearance for Ortho Sera suite of reagents that enabling extended antigen phenotyping for use with the Ortho Vision analyzer
Cleveland Diagnostics	Breakthrough device designation for blood-based prostate cancer test that evaluates structural changes to prostate-specific antigen (PSA) rather than just measuring the level of the biomarker a la traditional PSA tests

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FDA WATCH, *from page 3*

Manufacturer(s)	Product(s)
OraSure Technologies	Clearance for OraQuick Ebola Rapid Antigen Test, first US-approved rapid detection test for Ebola virus
BioMérieux	Clearance for ETest Eravacycline assay for determining antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria
Philips Electronics	received 510(k) clearance for Philips IntelliSite Pathology Solution (PIPS) with a modified display
Binding Site Group	Clearance for Human IgA liquid reagent kit for use on firm's Spaplus turbidimetric analyzer
Qingdao Hightop Biotech	Clearance for Pregnancy Rapid Test to measure human chorionic gonadotropin (hCG) in early pregnancy detection
Bioeasy Biotechnology	Clearance for Bioeasy Marijuana Test Dip Card and Bioeasy Marijuana Test Strip lateral flow immunochromatographic assays for preliminary detection of marijuana in urine
Beckman Coulter	Clearance for FC 500 MPL and MCL flow cytometers to measure biological and physical properties of cells and other particles as they pass through laser beams in a single file
Beckman Coulter	510(k) clearance for DxA 5000 total laboratory automation solution
Sekisui Diagnostics	510(k) clearance for Acucy Influenza A&B test + CLIA waiver for use on the Acucy Reader
Roche	De novo premarket review pathway clearance to market Cobas vivoDx MRSA test with Cobas vivoDx System
Seventh Sense Biosystems	Extension of existing 510(k) clearance for Tap push-button blood collection device, Tap, for use by laypersons and wellness testing at home
Sight Diagnostics	510(k) clearance for OLO finger prick blood tester
Personal Genome Diagnostics	Investigational Device Exemption (IDE) approval for use of its elio tissue complete assay in a Merck trial of pembrolizumab-based combination therapy
RightEye	Breakthrough device clearance for Parkinson's test
Foundation Medicine	Clearance for FoundationOne CDx test as a companion diagnostic for alpelisib (Novartis' Piqray) in combination with fulvestrant (AstraZeneca's Faslodex) for treatment of postmenopausal women, and men, with hormone receptor-positive, human epidermal growth factor receptor 2-negative, PIK3CA-mutated, advanced or metastatic breast cancer
Qiagen + DiaSorin	Clearance for Liaison QuantiFeron-TB Plus Test, an automated workflow and assay for latent tuberculosis detection
DiaSorin	Clearance for Simplexa VZV Swab Direct assay for qualitative detection of varicella-zoster virus DNA + use with firm's Liaison MDx instrument
BioMérieux	Clearance for received clearance for ETest Delafloxacin system

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Manufacturer(s)	Product(s)
Beckman Coulter	Clearance for Access PCT chemiluminescent immunoassay for measuring procalcitonin levels using firm's Access immunoassay systems
Beckman Coulter	Clearance for MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem
Siemens Healthineers	Clearance for Advia Centaur Cortisol chemiluminescent immunoassay for quantitative determination of cortisol in serum, plasma and urine, using firm's Advia Centaur XP system
Siemens Healthineers	Clearance for chemiluminescent Advia Centaur CA 15-3 assay to detect cancer antigen CA 15-3 in human serum and plasma using firm's Advia Centaur, Advia Centaur XP and Advia Centaur XPT systems
PerkinElmer	Clearance for GSP Neonatal Total Galactose kit for determination of total galactose concentrations in blood specimens dried on filter paper
Immunalysis	Clearance Carisoprodol Metabolite/Meprobamate Urine HEIA enzyme immunoassay for analysis of anxiety disorder therapy meprobamate
Sebia	Clearance for Capi 3 Immunotyping kit for detection and characterization of monoclonal proteins in urine and serum

Genetic Testing: NCCN Updates Genetic Breast, Ovarian & Pancreatic Testing Guidelines

On Dec. 4, the National Comprehensive Cancer Network (NCCN) issued updated guidelines for use of genetic testing to assess the risk of breast, ovarian and pancreatic cancer. The headliners of the new guidance include a new approach and organization that goes beyond BRCA mutations, broadening of existing pancreatic, breast and ovarian testing recommendations and continued skepticism about direct-to-consumer genetic testing. Here is a rundown of all the key points.

Changes in Approach

The NCCN has been issuing genetic testing guidelines since the BRCA genes were discovered two decades ago. Key structural changes in the revised guidelines include:

- Inclusion of information about new genes discovered after BRCA, including with regard to breast, ovarian and pancreatic cancer risk;
- Reorganization of the guidelines by disease and syndrome type; and

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NCCN Updates Genetic Breast, Ovarian & Pancreatic Testing Guidelines, *from page 5*

- Streamlined information about subsequent steps for people who meet genetic testing criteria.

Broader Criteria for Pancreatic Cancer Testing

The NCCN continues to recommend genetic testing for all pancreatic cancer patients but now has a greater recognition of the genetic risks associated with pancreatic cancer. Accordingly, the new testing guidelines are broader and include more information on the screening or management approaches clinicians should take with individuals who have pathogenic or likely pathogenic mutations in genes associated with pancreatic cancer, including not just BRCA1/2 but also other inherited gene mutations that studies have linked with high risk of pancreatic cancer, including:

- ATM;
- CDKN2A;
- MSH2;
- MLH1;
- MSH6;
- EPCAM;
- PALB2;
- STK11; and
- TP53.

"Based off of these data, there is now a compelling reason for all individuals with pancreatic cancer to be offered genetic counseling and germline testing for such variants—particularly given the possibility that their at-risk family members could greatly benefit from known, effective cancer risk-reducing interventions (e.g., surgical removal of the ovaries for female BRCA1/2 mutation carriers)," noted NCCN guideline panelist **Matthew B. Yurgelun, MD**., of the Dana-Farber Cancer Institute in Boston.

Broader Criteria for Cancer Testing of Ashkenazi Individuals

The NCCN also maintains its longstanding recommendation of genetic testing for individuals of Ashkenazi Jewish descent who have breast cancer or prostate cancer. But the revised guidelines broaden that recommendation to include testing for all individuals with Ashkenazi Jewish ancestry, regardless of family cancer history, within research studies for the three cancer-linked founder mutations in BRCA1/2 that show up in this population at increased rates. If they cannot participate in a research study, the guidelines say these individuals can receive commercial testing with appropriate pre- and post-test counseling and follow-up management. "Testing should not be offered outside of a

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medical framework or clinical trial," the NCCN cautions.

Continued Wariness Over DTC Testing

To the disappointment of consumer genetic testing laboratories, the NCCN experts who created the revised guidelines continued to throw cold water on direct-to-consumer genetic testing, stressing its limitations and the potential need for confirmatory testing. "More and more patients are presenting to clinic[s] having already had themselves tested through direct-to-consumer labs," **Robert Pilarski** from the Ohio State University Comprehensive Cancer Center and vice-chair of the guidelines panel noted in a statement. "Providers need to be aware that the tests offered by many of these labs are not equivalent to traditional genetic testing, and the results may need to be confirmed in another laboratory before being used for clinical care."

Precision Medicine: Are Primary Care Providers Prepared to Interpret Genetic Testing Results?

Specialists might be the best choice to interpret genetic testing results, but primary care providers may be positioned to do so when specialists are not available, a new study has found. And that is a finding of enormous importance given the inexorable rise of genomic testing and precision medicine.

The Diagnostic Challenge

Interpreting the results of genetic testing has become the domain of a specialized group of genetic counselors and clinical geneticists. But because these specialists are so few in number and spread so thin, the concern is that they will be quickly overwhelmed by the sheer volume of genetic data that requires analysis. The problem will become even more intense if and when today's direct-to-consumer genetic testing, which is largely not covered by health insurers, becomes accepted as a mainstream part of treatment. All of this raises an important question: Are primary care providers ready, willing and able to fill the void?

The Study

A team of researchers led by Biomedical Informatics Ph.D. **Dr. Scott McGrath** set out to answer that question by surveying 664 medical professionals, including both genetic specialists and primary care providers, about their feelings on deciphering genetic data for their patients. Did they feel comfortable with and capable of making an accurate assessment and explaining the results to patients? Respondents were asked to interpret genetic data under three scenarios:

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Are Primary Care Providers Prepared to Interpret Genetic Testing Results?, *from page 7*

- A scenario based on a 23andMe risk report on the genetic susceptibility to diabetes of a 35-year-old obese man;
- A scenario based on a Pathway Genetics drug response result for statin-induced myopathy for a man taking simavastatin to control his cholesterol; and
- A more complex scenario based on a report from Geisinger's COMPASS genomic testing tool involving symptoms and a genetic sequencing test result involving DCTN1 variants linked to distal hereditary motor neuronapathy type VIIB, for a 48-year-old woman with three children.

The Findings

The study, described in BMC Health Services Research, found that both specialists and primary care providers had generally high accuracy rates in interpreting the results of the three scenarios, with specialists averaging 83.4 percent correct and other primary care providers averaging 74.4 percent correct. Based on the relatively small magnitude of difference between the groups, the researchers concluded that primary care providers might, in fact, be able to interpret genetic testing results correctly when specialists are not available. Other key findings:

- Specialists were more confident than primary care providers in their ability to interpret testing results;
- While respondents from both groups were more likely to stumble on the third scenario involving a rare disease, specialists performed better in handling that scenario;
- Providers with genetic testing experience were twice as likely to correctly interpret the three scenarios;
- Younger providers who were more likely to be taught about genetics in medical school and residency were better able to interpret the three testing scenarios.

Takeaway: "The significance of this study is that it's the first time we've looked at how health professionals and genetic specialists interpret this data, not just the consumer," according to McGrath. The good news is that it suggests that when specialists are unavailable, primary care providers are prepared to take on the task of interpreting genetic data, despite their lack of specialized training and experience. However, the study also shows that having such training and experience significantly enhances their ability to interpret those results correctly.

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Proposed New Medicare Coverage Rules for NGS Germline Testing of Early-Stage Cancer Patients, *from page 1*

oncology panel tests also facilitate personalization of treatment by giving patients and providers a more comprehensive genetic profile of cancer and information relevant to potential cancer treatments.

The NGS testing at issue is germline NGS testing of BRCA1/2 genes. Such testing can be used to direct treatment of poly ADP ribose polymerase (PARP) inhibitors in advanced breast and ovarian cancer patients; but it can also be used at early stages to assess patients for their inherited risks for these and other cancers. Early-stage NGS germline testing results generate risk information that can be determining a patient's need for preventive screening and surgical interventions.

The Testing Controversy

However, the clinical benefits of early-stage NGS germline testing are less well documented than late-stage testing. Accordingly, CMS attempted to pump the brakes by issuing a National Coverage Determination (NCD) on late-stage testing that suggested early-stage testing should be restricted. Shortly thereafter, CMS instructed MACs to align their NGS testing policies in accordance with the new NCD. Earlier this year, one of the biggest MACs, Palmetto GBA, revised its Local Coverage Determination (LCD) for BRCA1 and BRCA2 genetic testing to restrict coverage for NGS panels when performed for individuals with early-stage disease to the detection of somatic mutations driving the cancer and bearing on personalization of treatment. Germline testing was left on the cutting room floor.

Genetic testing laboratories, providers and patient groups raised vocal objections to the new policy for harming early-stage cancer patients by depriving them of badly needed treatment options. CMS read the message loud and clear. And on Oct. 29, it issued a new coverage proposal to address the concerns.

The New Coverage Proposal

CMS has backed down and is now proposing to cover germline NGS testing for early-stage breast and ovarian cancer patients under certain conditions. "The evidence for cancers of the breast and ovary suggests that the use of NGS can identify germline mutations which can lead to better stratification of patients in the physician management of inherited cancers of the breast and ovary," the agency acknowledges while also noting that knowledge of germline mutations associated with increased inherited risk of breast and ovarian cancer can help tailor treatments for Medicare beneficiaries.

The 5 Coverage Conditions

While providing for coverage of NGS germline testing of early-stage cancer patients, the CMS proposal also would impose strict limitations. There are five coverage conditions:

1. The tests must be FDA-approved or -cleared.

2. The tests must be ordered by a treating physician.

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Proposed New Medicare Coverage Rules for NGS Germline Testing of Early-Stage Cancer Patients, *from page 9*

3. The patient for whom the tests are ordered must have:
   - Ovarian or breast cancer;
   - Clinical indications for germline (inherited) testing;
   - Risk factors for germline (inherited) breast or ovarian cancer; and
   - Not been previously tested using NGS.
4. The ordered NGS test must:
   - Have U.S. Food and Drug Administration (FDA) approval or clearance;
   - Be for an FDA-approved or -cleared indication; and
   - Generate results provided to the treating physician for management of the patient using a report template to specify treatment options.
5. The test must be performed by a CLIA-certified laboratory.

The proposal would also give MACs authority to make LCDs providing local coverage for physician-ordered NGS tests performed in a CLIA-certified laboratory that are *not* FDA-approved, including for patients with breast or ovarian cancer who also have risk factors indicating a need for testing for inherited cancers other than breast or ovarian cancer, provided that such patients have not previously received an NGS test.

What's Next?

CMS is slated to finalize the proposed national coverage determination on Jan. 27, 2020.

Takeaway: The Coverage Policy Is Half a Loaf, At Best

Although it is certainly an improvement, the new CMS coverage proposal does not go as far as genetic testing laboratories and other stakeholders would have liked.

First and foremost, the proposal is limited to testing for breast and ovarian cancer. According to the agency, there is limited evidence supporting the use of germline NGS testing for pancreatic cancer, mesothelioma, astrocytoma and other inherited cancers. "We believe that, for other cancers, the evidence is rapidly developing," CMS notes. "We are therefore maintaining the Medicare Administrative Contractors' discretion to make coverage decisions on diagnostic uses of NGS testing for patients with inherited cancers based on new evidence that may arise."

Even for breast and ovarian cancer, finding a covered test will be tricky. According to reimbursement expert ***Bruce Quinn****, no germline NGS test currently on the market meets all the national coverage criteria:*

- *Myriad Genetics' BRACAnalysis CDx is FDA-approved but not an NGS test;*
- *While FDA-approved, Myriad's NGS test myChoice CDx for analyzing*

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BRCA1/2 genes is a somatic rather than germline test;

- *The Myriad MyRisk NGS panel is a germline test but has not been FDA-approved; and*
- *Foundation Medicine's FoundationOne CDx and FoundationFocus BRCA test are NGS and FDA-approved, but are not germline tests.*

Another problem pointed out by Quinn is the restriction that patients not have any prior NGS testing which excludes patients from getting germline testing after having previously received somatic NGS testing.

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New Study Supports Feasibility of At-Home Urine Prostate Cancer Testing

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But perhaps PUR's greatest benefit is that it can be performed on urine samples collected at home. The PUR test uses a commercial preservative allowing samples to be maintained at room temperature without loss of RNA quality.

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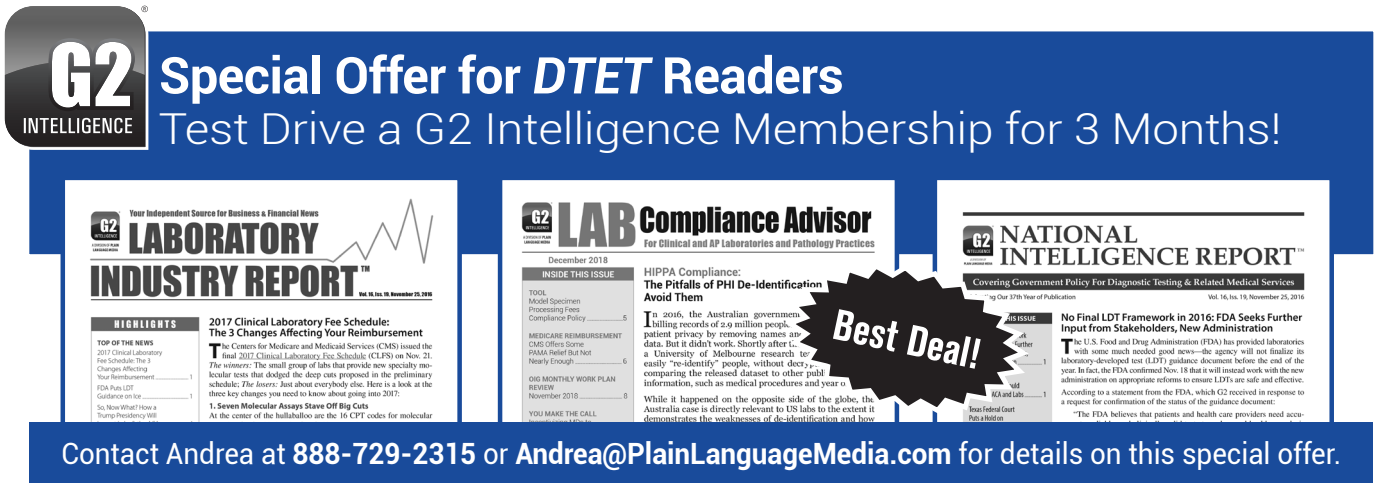

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