



Life Science Tools & Diagnostics

OB/GYN Survey: NTRA Builds Lead, Views on USPSTF Cervical Screening for HOLX

In March 2024, we performed a survey of n=36 OB/GYNs to gauge expectations on several hot topics – including the outlook for demand, implications for market share from InVita's bankruptcy, and the USPSTF impact on cervical cancer screening. It has been 2 years since our last OB/GYN survey (March 2022), and much has changed in the market and competitive landscape. For some of our questions on demand and market penetration, we have longitudinal datapoints we reference. **Public companies in focus include DGX, HOLX, LH, MYGN & NTRA.**

1) Favorite Lab – Natera Extends its Lead: To start, we asked respondents who their #1 preferred lab is to work with. **Natera was selected #1 by 17 respondents (47%),** which compares to 26% in our 1Q22 survey, and 17% in a survey we ran in 3Q21. **LabCorp finished in 2nd, selected as #1 by 8 respondents (22%).** Their rank has been fairly steady vs 19% in our 1Q22 survey, but down from 27% in our 3Q21 survey. **Myriad finished in 3rd, selected as #1 by 5 respondents (14%).** This is down from 16% in our 1Q22 survey, and 17% in our 3Q21 survey. **Quest was selected #1 by 8% of respondents,** down from 13% in our 1Q22 survey and 17% in our 3Q21 survey. **InVita has been a clear share donor,** selected #1 by 3% of respondents, down from 19% in our 1Q22 survey and 10% in our 3Q21 survey.

2) Volume Growth – Expectations Remain Positive: Using our weighted average, NIPT led the pack at 10% expected volume growth, followed by carrier screening and HCT rounding up to 10%, then polypectomy/fibroid removal at 8% (relevant for HOLX MyoSure), cervical cancer screening at 7%, and endometrial ablation at 4% (relevant for HOLX NovaSure). **We also provide views on NIPT penetration, carrier screening expanded panels, and RhD testing demand.**

3) NVTB Bankruptcy - NTRA the Biggest Share Gainer: Next, we asked several questions to try and tease out the impact of InVita's bankruptcy on market share for women's health testing. InVita's overall share was quoted at 17-18% across carrier screening, NIPT and HCT by the respondents in our survey, but we think this is likely over-stated relative to actual share. **Natera is expected to be the big winner of market share gains. In NIPT,** of the 12 OB/GYNs that work with InVita today, 7 (or 59%) plan to shift their volume to Natera. 5 other labs each got 1 response, including BillionToOne, LabCorp, Myriad and Quest. **In HCT,** of the 13 OB/GYNs that work with InVita, 4 (or 31%) plan to shift their volume to Natera. Ambry got 3 responses (23%), Myriad and "Other" got 2 responses (or 15%), while BillionToOne and LabCorp got 1 response.

4) Cervical Cancer Screening - Share Shift Looks Manageable for HOLX if USPSTF Places a Priority on HPV Primary (Over Co-testing): As we continue to await the USPSTF's draft recommendation, we polled OB/GYNs on expectations for share shift if a priority is placed on HPV primary over co-testing (our base case). **Our survey highlights how popular co-testing is with physicians today, and why it is likely difficult for the USPSTF to get rid of the standard of care. Today,** in our survey, 71% of volume is co-testing, 16% with Pap only, and 13% with HPV primary. Note, HOLX estimates that only 1-2% of the market is HPV primary today (respondents in our survey likely overstated that). **If USPSTF places a priority on HPV primary,** share shifts to 61% co-testing (-10% from today), 11% Pap only (-5%), and 29% HPV primary (+16%). **We view the results as reassuring for the HOLX Bulls.** Bears have argued that co-testing deteriorate much further if doctors follow the guidelines religiously.

Please see important disclosures at the end of this report.

MARCH 18, 2024

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Nephron OB/GYN Survey

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Survey Screening Criteria

To participate, we screened for OB/GYN's that self report seeing >500 patients per year, order testing from at least ONE of EXAS, MYGN, NTRA and NVTA, and they must perform NIPT, HCT and cervical cancer screening. Given we wanted respondents that perform these tests, it might overstate the level of market penetration we quote in the NIPT section.

Before jumping in, we caveat from our experience, respondents are always positively biased. We try as hard as we can to ask questions in a manner to get the most accurate answer as possible... but we've found an inherently positive bias across all surveys over time. As such, we're more interested in the relative change in expectations vs absolute levels.

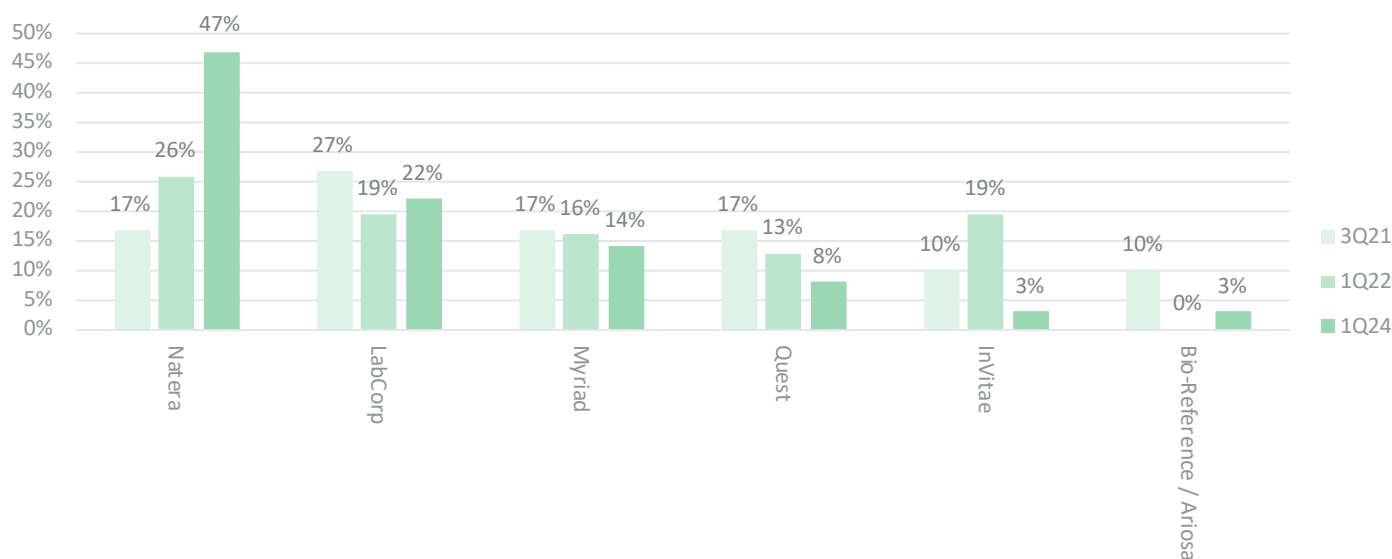
1) Favorite Lab: Natera Extends its Lead

To start, we asked respondents who their #1 preferred lab is to work with.

Natera was selected #1 by 17 respondents (47%), which compares to 26% in our 1Q22 survey, and 17% in a survey we ran in 3Q21. LabCorp finished in 2nd, selected as #1 by 8 respondents (22%). Their rank has been fairly steady vs 19% in our 1Q22 survey, but down from 27% in our 3Q21 survey. Myriad finished in 3rd, selected as #1 by 5 respondents (14%). This is down from 16% in our 1Q22 survey, and 17% in our 3Q21 survey. Quest was selected #1 by 8% of respondents, down from 13% in our 1Q22 survey and 17% in our 3Q21 survey. Invitae has been a clear share donor, selected #1 by 3% of respondents, down from 19% in our 1Q22 survey and 10% in our 3Q21 survey.

We think Natera has been a notable share gainer over the last few years in NIPT. In September 2020, ACOG initially announced a supportive recommendation for average risk NIPT testing. In June 2021, Progenity exited their reproductive health testing business. In late 2022, Sema4/GeneDx exited the reproductive health business. In January 2024, Invitae announced it was selling its reproductive health assets to Natera. Over this period of time, we estimate Natera's NIPT market share has increased from around 33% to >55%.

Fig. 1: "Overall, which is your #1 Preferred Lab to order women's health testing from?" (n=36)



Source: Nephron Research

Fig. 2: “For your #1 Preferred Lab: Why is this your favorite laboratory for women’s health testing?”

State	For your #1 Preferred Lab: Why is this your favorite laboratory for women’s health testing?
Natera	
CA	Natera took over
CA	I send most of my NIPT and carrier testing screens to Natera because they are cheaper for the patients, Natera has a discount deal for patients in my p
FL	Best lab for NIPTS due to SNP-based technology versus other labs which perform massive parallel sequencing
FL	Our affiliate lab. #1 for NIPT Natera. #1 for genetic cancer testing Myriad
FL	It depends on the testing ordered
IL	Excellent customer service. Easy to interpret results. They cover Medicaid for the most part.
MA	Tech leader
NJ	They have excellent sensitivity and specificity rates
NV	Easiest to use
NY	Patient portal, access to genetic counseling, rep support
NY	They have published more seemingly reliable data than other labs in NIPT. Also, best economic fit for patient population.
NY	Excellent customer service, reliable results. Strong rep who provides a lot of service to our office.
NY	Best customer service
NY	I use it frequently for NIPT. Fast turnaround time and any issues they resolve quickly
TX	They were providing tests regardless of ability to pay
TX	Best test
VA	They are easy and provide the genetic tests we would need
LabCorp	
FL	Easier to get covered
FL	Reimbursement
IL	Accuracy and customer service for their NIPT (cfDNA) product.
MD	Insurance requirement
NC	Slight preference
NC	We send to LapCorp and Myriad.
NJ	NGS technology used, fewer no calls, quick turn-around time, give large discount to non-insured patients
NY	Has diagnostic and screening options
Myriad	
CA	Reports
CA	We have a contract with Myriad
CT	Good rapport with our rep for abnormal results
NY	Myriad has the largest database
SC	High quality
Quest	
CA	This is where we send our patients
GA	Convenience.
MO	Overall variety of tests
BillionToOne	
IL	Exemplary service, genetic counseling, one step Unity carrier screening, eliminating need to pursue paternal testing in case of +carrier for mother
Bio-Reference / Ariosa	
MA	Based on turn around
InVitae	
CA	Logistics, Larger panel, Support

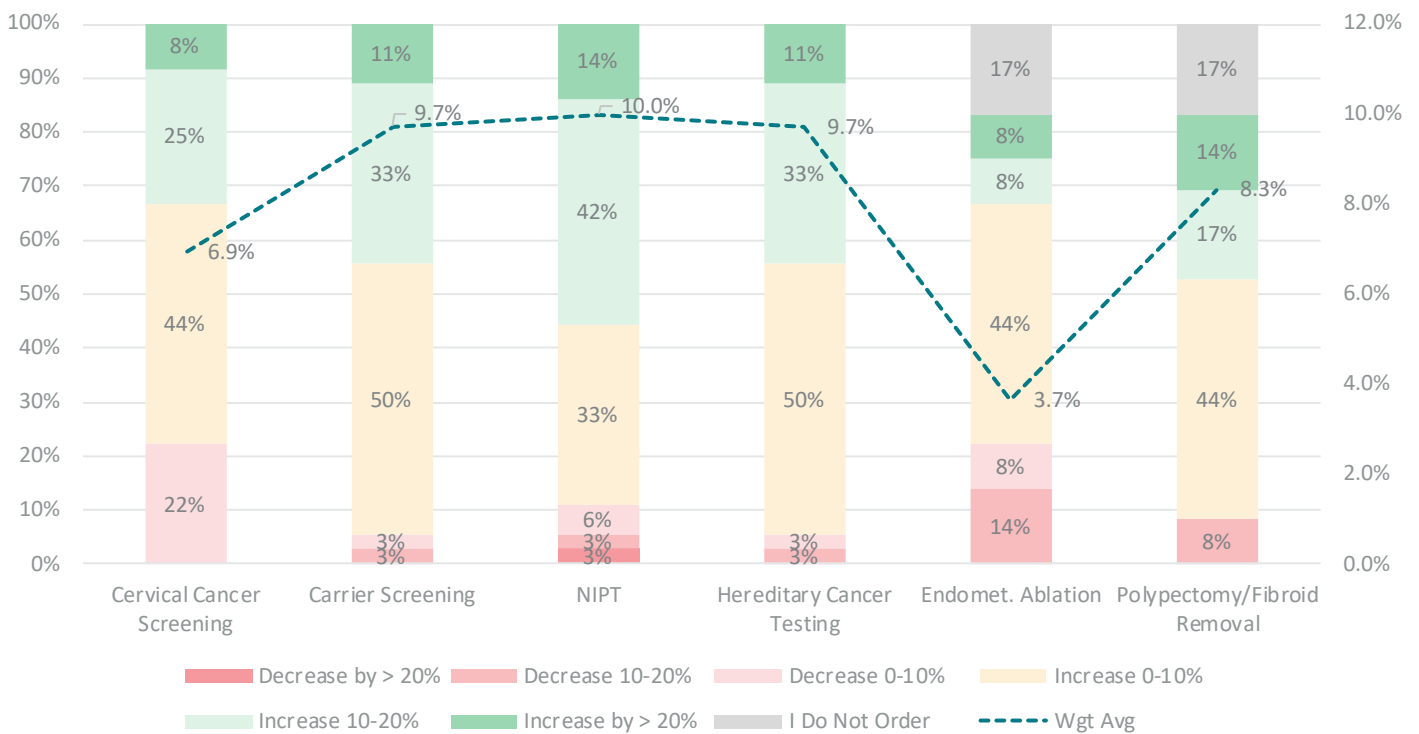
Source: Nephron Research

2) Volume Growth: Expectations Remain Positive

Next, we polled respondents on volume expectations over the next year for cervical cancer screening, NIPT, carrier screening, HCT, endometrial ablation (relevant for HOLX NovaSure) and polypectomy/fibroid removal (HOLX MyoSure). We asked respondents to select amongst 6 choices, "Increase by >20%," "Increase 10-20%," "Increase 0-10%," and so on. We took a sum-product of the results to estimate volume growth, using 25% for >20%, 15% for 10-20%, 5% for 0-10%, and so on.

Every category was positive. Using our weighted average, NIPT led the pack at 10% expected volume growth, followed by carrier screening and HCT rounding up to 10%, then polypectomy/fibroid removal at 8%, cervical cancer screening at 7%, and endometrial ablation at 4%. The results are not that surprising, but reassuring that the volume backdrop remains positive. The relative growth of polypectomy/fibroid removal relative to endometrial ablation is consistent with HOLX commentary around relative growth of MyoSure vs NovaSure.

Fig. 3: "In the next year, how do you expect your rate of volume growth will be for these tests/procedures?" (n=36)



Source: Nephron Research Weighted Average is a sum product of responses with 25% for >20%, 15% for 10-20%, 5% for 0-10%

Note: We excluded participants from the "weighted average" calculation if they "do not order"

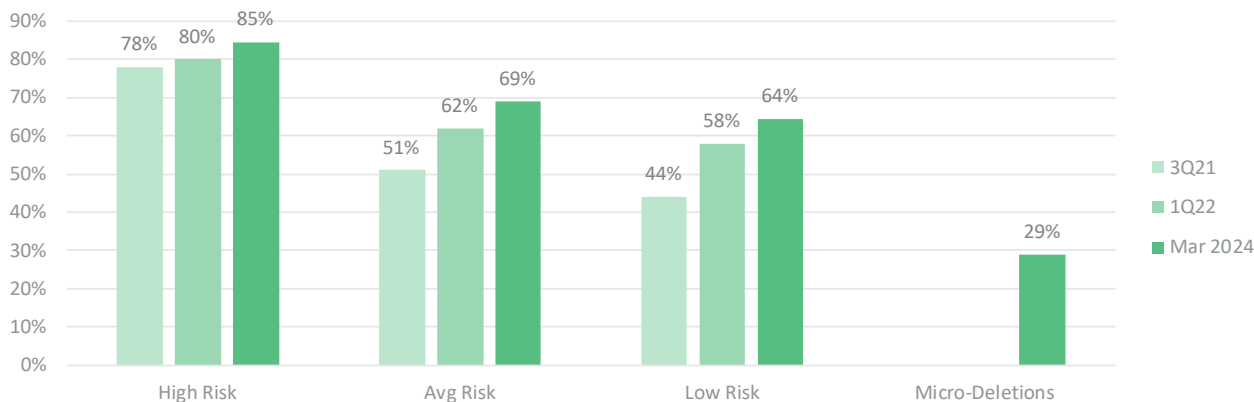
A) NIPT: Seeing Market Penetration Move Higher

For NIPT, we asked what percentage of patients physicians order NIPT testing for across high risk, average risk and low risk... and also how often they order micro-deletion testing.

Across the board, penetration has moved higher relative to our prior surveys:

- **In High Risk**, the OB/GYNs in our survey estimate they order testing for 85% of patients (vs 80% in our 1Q22 survey, and 78% in our 3Q21 survey).
- **In Average Risk**, the OB/GYNs in our survey estimate they order testing for 69% of patients (vs 62% in our 1Q22 survey, and 51% in our 3Q21 survey).
- **In Low Risk**, the OB/GYNs in our survey estimate they order testing for 64% of patients (vs 58% in our 1Q22 survey, and 44% in our 3Q21 survey).
- **For micro-deletions**, the OB/GYNs in our survey estimate they order testing on just 29% of their NIPT orders. 6 respondents (17%) order micro-deletions for 0% of their patients. **NOTE:** Natera estimates 75% of their tests include micro-deletions, and we estimate they have >55% market share. Our survey results screens as understated relative to what market data would suggest.

Fig. 4: “In NIPT, what percentage of pregnancies do you order testing for? How often do you order micro-deletion panels?”



Source: Nephron Research

Fig. 5: “Please explain your view on the value of micro-deletion testing (including 22q11.2, DiGeorge syndrome)”

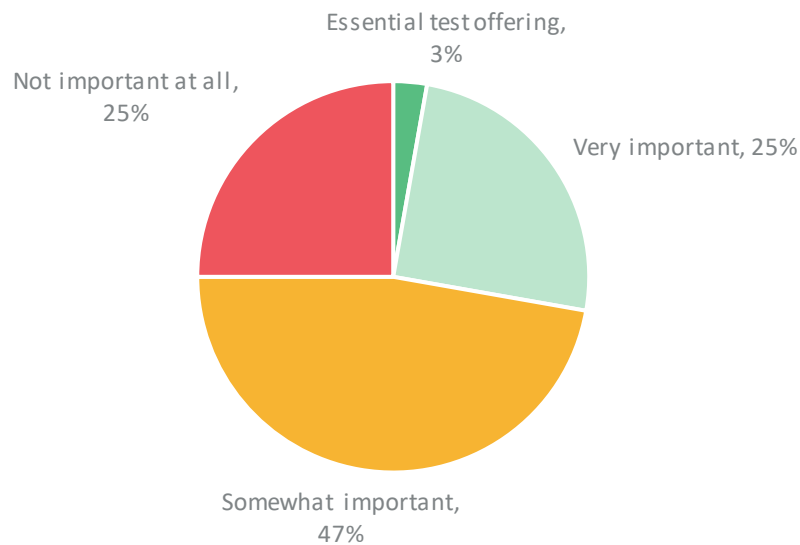
State	% of NIPT	Please explain your view on the value of micro-deletion testing (including 22q11.2, DiGeorge syndrome):
MA	100	Based on what is covered and risk of patients
NY	100	Doing this years before ACOG guidelines
NY	100	I order for all my patients . It has become standard of care for all OB patients
TX	100	Important
NY	90	We offer MD panels to all pts with their NIPT; a small percentage decline due to their concerns about false positives.
CT	50	I screen everyone unless they decline
NJ	50	These are averages
NV	50	It really depends on what the patient wants. I offer to everyone and provide risks, benefits, alternatives, and indications to help patients decide
NY	50	I don't recommend. I offer it to patients, and "high-risk" patients are more likely to prefer it, even though there is no age based association with CNVs.
TX	50	Depends on coverage
GA	40	Early diagnosis, accurate diagnosis, risk assessment, tailored medical management.
FL	35	The data on microdeletion testing accuracy is still developing but has been somewhat disappointing; we send microdeletion panels on patients that have suspicious family histories or desire such testing with or without a a discernible history.
NY	30	For high risk patients only
NC	25	We work with genetic counselors for the micro-deletion panels.
CA	20	Very important to screen. No coverage unless specified situation
FL	20	Varies widely
IL	20	Microdeletion panels are only useful if fetal anomalies are noted on ultrasound at this time.
MA	20	Patient driven
MD	20	I order NIPT for all patients who want to be tested.
NJ	20	ACOG recommends against microdeletion panels for every patient, we order the core tests i.e. sickle cell, SMA, Fragile X, but do not order microdeletion panels for all patients - We order these based on family and prior obstetrical history
CA	10	Based on clinical risk factors and suspicion of genetic risk
NY	10	We use as part of our standard panel. Patient are counseled on PPV and NPV of testing
VA	10	Usually NIPT for high risk but also done in lower risk tiers
FL	5	N/A
MO	5	Rare occurrence and only if based on history or referral from genetics
NC	5	N/A
SC	5	Microdeletions are of value if the patient has a previous affected child with a microdeletion
CA	2	Almost all patients get NIPT
IL	2	Microdeletion testing can be done with patients with abnormal prior hx, family history, ultrasound abnormalities on Level II u/s, quad screen abnormal results.
FL	1	MFM usually orders Microdeletion panels when indicated
CA	0	Not covered by state
CA	0	The sensitivity and specificity of the microdeletion testing is not high enough for me to value this test
CA	0	Genetic counselors order supplementary if needed
FL	0	Don't really use those
IL	0	Apart from del22q11.2, there are no standard recommendations for screening other microdeletions through cfDNA.
NY	0	Only order 22q deletion after counseling but not panels

Source: Nephron Research

B) RhD Testing: Amidst Shortage, RhD Testing is Somewhat Important

As a new question, we polled OB/GYNs on their views on RhD testing amidst a shortage of [Rho\(D\) immune globulin announced by the FDA in February](#). 47% of respondents say RhD testing is "Somewhat important," with mixed results from the rest of respondents. On one hand, 25% of respondents say it is "very important," and 3% (1 respondent) said it was essential. On the other hand, 25% of respondents said it is "not important at all."

Fig. 6: "For NIPT testing, how important is it to have fetal RhD testing available to your patients? (n=36)



Source: Nephron Research

Fig. 7: “Please explain your view on the value of fetal RhD testing:”

State Please explain your view on the value of fetal RhD testing:	
Essential test offering	
NY	Every pregnant pt needs to know
Very Important	
CA	Rhogam shortage
CA	Easy to treat and prevent complications
CA	This can decrease administration of Rhogam injection for Rh negative patients
FL	Yes
GA	Inclusion of fetal RhD testing in NIPT can offer additional benefits to patients, especially for those at risk of RhD alloimmunization
IL	Would be easy to order RhD testing on the same panel so it doesn't have to be a separate sendout.
IL	Rh neg moms approx 15% of our population, though alloimmunized fetuses fortunately are less common.
MA	High efficacy and sensitivity
NJ	For Rh negative non sensitized mothers it saves a lot of invasive procedures and further testing if fetal Rh factor is known, e.g. if fetus is Rh negative then no further testing is required
Somewhat important	
CT	Only relevant in certain cases
FL	Not a common occurrence
FL	I believe third party payors will increasingly request NIPT results for fetal RhD testing before deciding to pay for prophylactic Rhogam injections.
FL	Don't really use that
FL	N/A
MA	Not routine in US
MD	Most patients are Rh positive.
MO	Maybe helpful to determine in Rh negative patients that there is no need for Rhogam administration
NC	This would only be important in Rh- patients; could see a model, depending on cost, where having this information would prevent the need for Rhogam.
NJ	Important prognosticator
NV	Only if patient is Rh negative
NY	This is not as essential as thought unless there is an Rh issue
NY	Oftentimes spouses (male) are unaware of blood type. Given instances of rhogam shortages across the country, there is value in knowing fetal rhd to limit overuse of rhogam administration
NY	Since it wouldn't eradicate the need to give rhogam unless it was a validated test-it's not critical.
NY	For patients who decline diagnostic testing
TX	It is helpful
VA	Not certain
Not important at all	
CA	It would be nice but not crucial
CA	Guidelines
CA	Not needed
IL	This is only done in our practice when someone has a positive antibody screen.
NC	N/A
NY	Relatively few patients are Rh(D) negative, and there is no Rhogam shortage in my area.
NY	Don't see the clinical need. We follow using traditional methods
SC	Already done with blood typing and only needs to be done in first pregnancy unless looking for irregular antibodies
TX	Not relevant

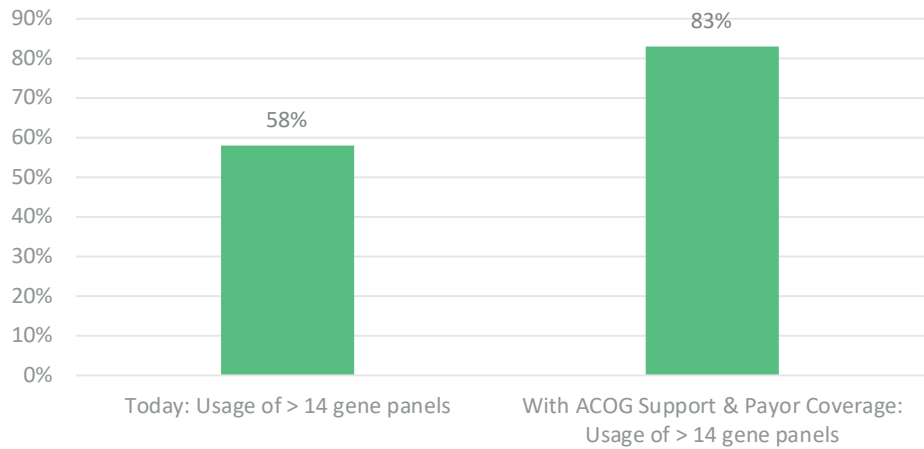
Source: Nephron Research

C) Carrier Screening: ACOG Support and Broad Payor Coverage Would Lead to More Expanded Panel Usage

Finally, we asked OB/GYNs around their usage of expanded panels for carrier screening today, and how that would change with ACOG guideline support and broad payor coverage.

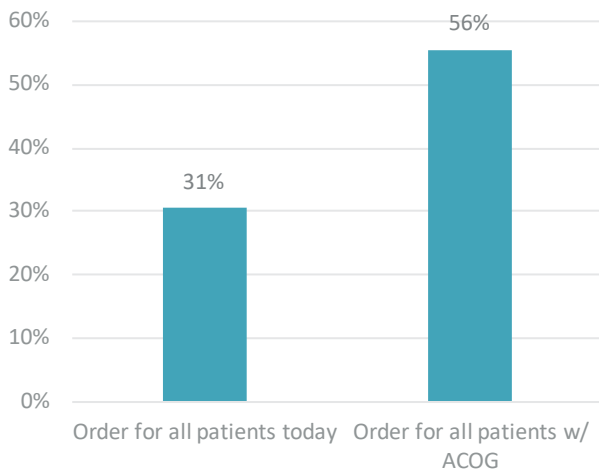
Physicians estimate they order expanded panels for a majority of their patients today (58%). This would increase higher to 83% with ACOG guideline support and broad payor coverage.

Fig. 8: “In carrier screening, what percentage of the tests that you order utilize expanded panels (>14 genes) today?” And “How would this change with ACOG guideline support and broad payor coverage?”



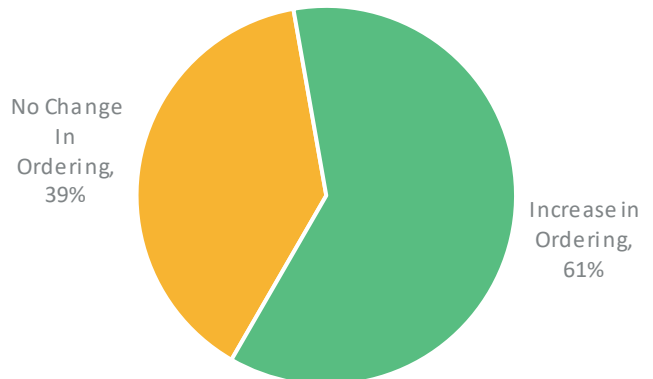
Source: Nephron Research

Fig. 9: The # of Respondents Who Order Expanded Panels for 100% of Patients Would Increase from 31% to 56% w/ ACOG Guideline Support & Broad Payor Coverage



Source: Nephron Research

Fig. 10: 61% of Respondents Will Increase Ordering of Expanded Panels w/ ACOG Guideline Support & Broad Payor Coverage



Source: Nephron Research

Fig. 11: “Please describe how ACOG guidelines and payor coverage would influence your carrier screening ordering:”

State	Today	w/ ACOG Support & Coverage	Change	Please describe how ACOG guidelines and payor coverage would influence your carrier screening ordering:
FL	0	100	100	Would use if it was covered approved by ACOG
CA	10	100	90	Would be great to screen more
IL	20	100	80	If ACOG supports increased carrier screening, then I would follow their recommendations.
CA	30	100	70	If this test is covered by insurance I think it should be used to its maximum potential
NJ	50	100	50	> 14 gene panels are increasing almost year to year
TX	50	100	50	If supported I would order it
GA	75	100	25	ACOG guidelines and payor coverage influences everything.
NY	75	100	25	I prefer to order ACMG tier 3 or 4 screening based on patient risk factors
NY	90	100	10	We would probably just offer one standardized test if ACOG came out with a recommendation for a specific panel.
CA	100	100	0	Most of our pts prefer full panel testing
FL	100	100	0	As a perinatologist with genetic counselors, we only send expanded carrier panels
FL	100	100	0	Just switched to extended 14 genes screen
IL	100	100	0	It is our standard to offer carrier screening panels > 14 genes in all prenatal and preconception patients.
MA	100	100	0	Quality measure for us
NC	100	100	0	This is already the standard at my institution
NV	100	100	0	I prefer to offer patients the most comprehensive panels possible
NY	100	100	0	Doing this year before ACOG guidelines
NY	100	100	0	I will always follow ACOG guidelines
TX	100	100	0	More info is better
VA	100	100	0	I do full genetic carrier screening tests
MD	50	90	40	Many patients do not want to pay for it; some do not want these results.
NY	90	90	0	I offer expanded carrier testing to all patients already, with very high uptake. This will not change based on ACOG guidelines.
MA	85	85	0	Based on what insurance covers
IL	10	80	70	Expanded panels only present in 10% of our NIPT testing today, but would be helpful if payor coverage were to be expanded.
CA	70	80	10	Cost factors
NY	50	75	25	Payor coverage limits a lot of genetic screening that is done. I find that oftentimes patients are unaware of risks of carrier status
CT	50	75	25	With ACOG support would be better coverage
FL	35	75	40	Estimated
NY	35	65	30	It will have an impact if it comes from ACOG
NC	5	50	45	I suspect more patients will ask for it if it is covered. There doesn't yet seem to be sufficient data on how to act on information ga
NJ	20	50	30	We would still not order for all patients, we would order based on family and personal obstetrical history
MO	35	50	15	With coverage more patients may accept
CA	40	40	0	No effect
FL	0	30	30	N/A
CA	2	30	28	Depends on cost.
SC	10	20	10	Very dependent on pending legal issues after Dodds

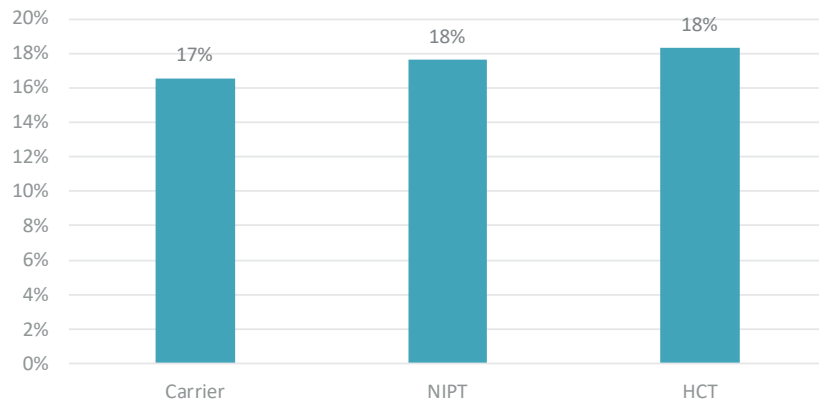
Source: Nephron Research

3) NVTA Bankruptcy: NTRA the Biggest Share Gainer

Next, we asked several questions to try and tease out the impact of InVitaе’s bankruptcy on market share for women’s health testing. “For InVitaе: What portion of your volume for different tests did you send their lab?” “How does InVitaе’s announced bankruptcy impact your practice?” “For NIPT and HCT: For volume you have been sending to InVitaе, which is the #1 lab you intend to shift volume to?”

Of the 36 respondents, 17 (47%) currently work with InVitaе for at least one test across carrier screening, NIPT and HCT. InVitaе’s overall share was quoted at 17-18% across carrier screening, NIPT and HCT by the respondents in our survey, but we think this is likely over-stated relative to actual share.

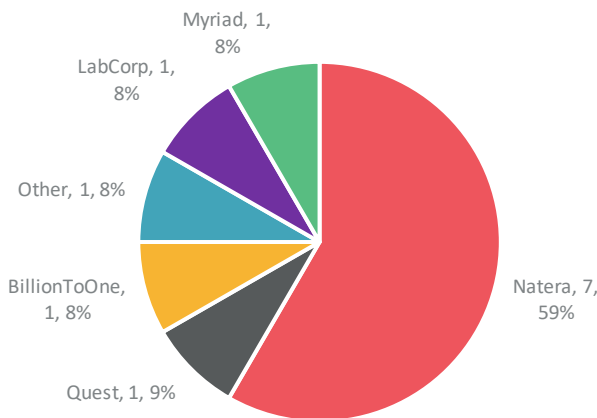
Fig. 12: NVTA Market Share Across Test Categories (n=36)



Source: Nephron Research

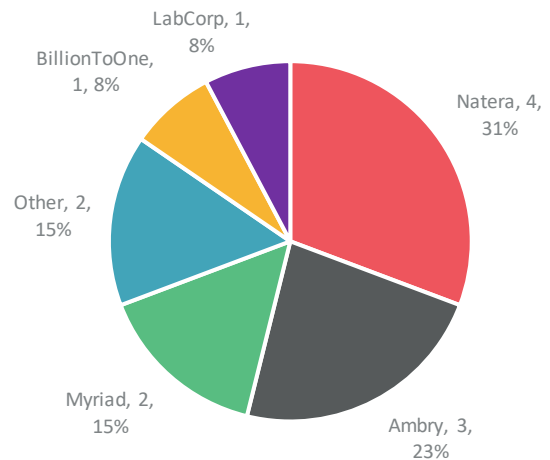
Natera is expected to be the big winner of market share gains. In NIPT, of the 12 OB/GYNs that work with InVitaе today, 7 (or 59%) plan to shift their volume to Natera. 5 other labs each got 1 response, including BillionToOne, LabCorp, Myriad and Quest. In HCT, of the 13 OB/GYNs that work with InVitaе today, 4 (or 31%) plan to shift their volume to Natera. Ambry got 3 responses (23%), Myriad and “Other” got 2 responses (or 15%), while BillionToOne and LabCorp got 1 response.

Fig. 13: NIPT: For Labs That Use NVTA, #1 Lab They Plan to Shift Volume To (n=12)



Source: Nephron Research

Fig. 14: HCT: For Labs That Use NVTA, #1 Lab They Plan to Shift Volume To (n=13)



Source: Nephron Research

Fig. 15: “For InVitaе: What portion of your volume for different tests did you send their lab?”... “How does InVitaе’s announced bankruptcy impact your practice?” ... “For NIPT and HCT: For volume you have been sending to InVitaе, which is the #1 lab you intend to shift volume to?”

State	Current Share to NVTA			How does InVitaе’s announced bankruptcy impact your practice?	NIPT New Lab Why?		HCT New Lab Why?	
	Carrier	NIPT	HCT					
CA	100	100	100	Concern about support	Quest	My group choice	Natera	Good support from genetic counseling
CA	0	0	100	I have been sending most of my testing to Natera, except HCT I have to find an alternate lab			Ambry	Ambry has a package beneficial to patients
NY	0	0	100	I heard that Natera is going to acquire them, not sure if they will exist as their own entity.			Ambry	Not sure.
CA	76	100	75	They were reliable and cheap	BillionToOne	I like their rhogam testing	BillionToOne	As above
NY	50	75	65	InVitaе was being used for our office in 40% cases	Natera	Natera has taken over	Myriad	Used Myriad a lot
MA	45	55	55	Depends on what is covered	Other	Do not use currently	Other	Do not use currently
IL	20	0	50	It would primarily affect our cancer testing. There are other labs that we work with.			Ambry	Good experience with them.
FL	30	30	40	N/A.	LabCorp	Easier to get covered	LabCorp	Easier to get covered
CA	100	100	30	No longer in business. Natera bought it	Natera	Took over InVitaе	Natera	Natera took over
MA	10	10	25	Contracted with Natera	Natera	Contracted with Natera	Natera	Contracted with Natera
FL	20	20	10	Will likely shift all this testing to other labs	Natera	Like their technology best	Myriad	Like reports and customer service
NY	10	10	5	Dying lab	Natera	Once InVitaе goes out of business	Natera	Once InVitaе goes out of business
FL	0	0	5	Not much			Other	Yes
NC	0	100	0	N/A.	Natera	N/A		
FL	100	0	0	Unsure about other provider labs				
NJ	35	30	0	N/A.	Natera	Excellent sensitivity and specificity rates		
SC	0	5	0	Contract driven	Myriad	High quality		
IL	0	0	0	I typically use Natera.				
GA	0	0	0	Don't use InVitaе.				
NJ	0	0	0	We do not send to InVitaе				
MO	0	0	0	Do not use				
NY	0	0	0	We dont use invitae				
CA	0	0	0	I don't order it				
NY	0	0	0	I don't use this lab.				
NV	0	0	0	I've always preferred different companies				
VA	0	0	0	I have not been ordering invitae				
IL	0	0	0	Did not use InVitaе				
MD	0	0	0	N/A.				
FL	0	0	0	N/A.				
TX	0	0	0	Do not sue				
NY	0	0	0	Didn't use				
CA	0	0	0	We don't use InVitaе				
NY	0	0	0	We do not use InVitaе				
NC	0	0	0	We do not use InVitaе				
CT	0	0	0	Don't use it				
TX	0	0	0	Not at all				

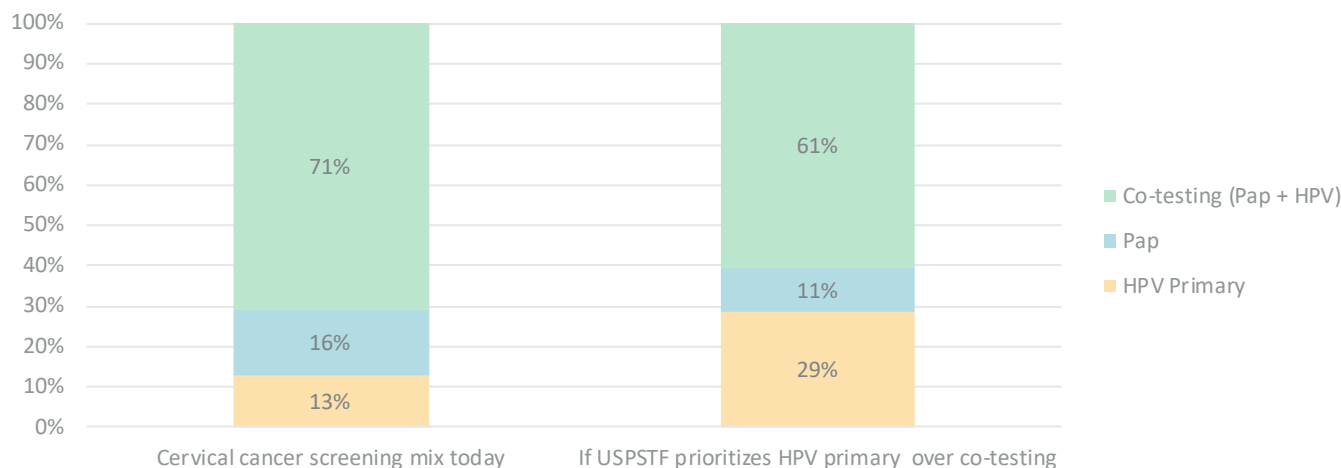
Source: Nephron Research

4) Cervical Cancer: Share Shift Looks Manageable if USPSTF Places a Priority on HPV Primary (Over Co-testing)

As we continue to await the USPSTF's draft recommendation on cervical cancer screening, we polled OB/GYNs on expectations for share shift if the guideline group places a priority on HPV primary over co-testing. As a reminder from our HOLX report on 10/2/2023, this is our base case scenario. Today, both testing methods have a grade A recommendation from the USPSTF. Before jumping in, we note that any changes to draft guidelines will then enter a comment period which could take a year, and then longer to filter through payor coverage decisions, and longer for health systems to re-evaluate their recommended testing strategies.

Our survey highlights how popular co-testing is with physicians today, and why it is likely difficult for the USPSTF to get rid of the standard of care. Today, respondents estimate they send 71% of their volume to co-testing, 16% with Pap only, and 13% with HPV primary screening. Note, HOLX estimates that only 1-2% of the market is actually HPV primary screening today. If USPSTF places a priority on HPV primary, respondents estimate they will still run 61% of screenings with co-testing (-10% from today), 11% with Pap only (-5%), and 29% with HPV primary (+16%). We view the results as reassuring for the Bulls. Bears have argued that co-testing deteriorate much further if doctors follow the guidelines religiously.

Fig. 16: “In cervical cancer screening, what is your mix of screening modalities today in your practice?” And “If USPSTF guidelines changed to prioritize HPV primary screening over co-testing, how would you shift your mix of screening (if at all)?”

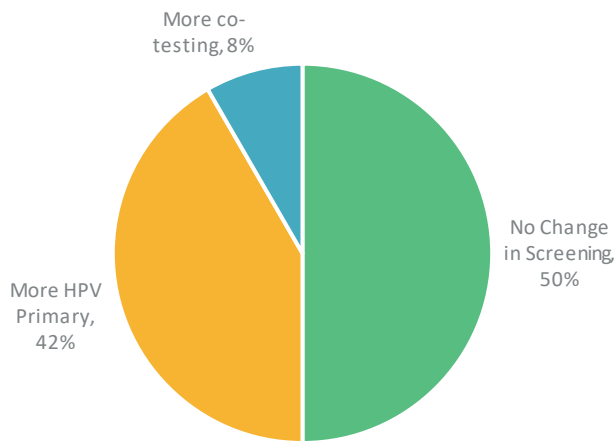


Source: Nephron Research

Looking at the individual responses, 50% of respondents plan to keep doing what they're doing in terms of screening even if USPSTF places a priority on HPV primary. 42% plan to run more HPV primary, while 8% interestingly say they will run more co-testing.

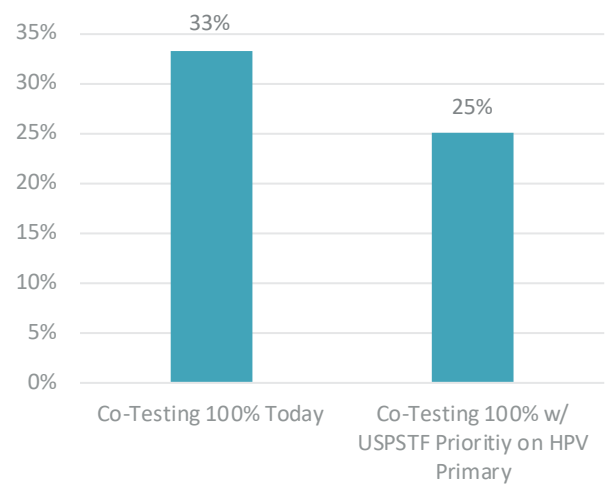
Interestingly, 25% of respondents expect to still run 100% of their screenings with co-testing even if USPSTF places a priority on HPV primary (down from 33% today, but far from zero). In the qualitative feedback, OB/GYNs expressed skepticism on the value of HPV Primary or Pap results alone, and view co-testing as providing the most complete answer.

Fig. 17: 50% of Respondents Will Not Change Their Screening Method if USPSTF Places a Priority on HPV Primary, 42% Will Run More HPV Primary, 8% More Co-Test



Source: Nephron Research

Fig. 18: The # of Respondents Who Use Co-Testing for 100% of their Patients Today Declines from 33% Today to 25% if USPSTF Places a Priority on HPV Primary (n=36)



Source: Nephron Research

Fig. 19: Qualitative Feedback on Preferred Cervical Cancer Screening Methods, and Impact of USPSTF Guidelines

State	Pap testing	HPV Primary	Co-testing	For your preferred method, please explain why this is the case:	Pap testing	HPV Primary	Co-testing	Change in Pap	Change in HPV	Change in co-test	Please explain how USPSTF guidelines influence your ordering decisions:
CA	0	0	100	Group guidelines	0	40	60	0	40	-40	Based on hypothetical recommendations I change practice
CT	0	0	100	For patients over 30	0	10	90	0	10	-10	There is value in cytology
FL	0	0	100	Concerned about sensitivity of a cotest alone	0	0	100	0	0	0	Concerned about sensitivity of a cotest alone
MA	0	0	100	Quality measre	0	0	100	0	0	0	Quality measre
MD	0	0	100	I do not feel that either test alone provides complete information.	0	0	100	0	0	0	I do not feel that either test alone provides complete information.
MO	0	0	100	Best option	0	0	100	0	0	0	USPSTF has failed over the years in their guidelines
NC	0	0	100	We follow the ASCCP and USPSTF guidelines for screening/management	0	100	0	0	100	-100	Our collection strategy would be the same; the lab would just run paps on HPV+ wome
NJ	0	0	100	Co-testing is most inclusive	0	0	100	0	0	0	Stays the same
NY	0	0	100	Highest yield for picking abnormal	0	100	0	0	100	-100	Insurance will mandate it that way
SC	0	0	100	Both offer better sensitivity and specificity	0	0	100	0	0	0	No change
TX	0	0	100	This is now our preferred method	0	0	100	0	0	0	It's what we are doing already
TX	0	0	100	Best	0	0	100	0	0	0	Uncertain--would need to see data
NJ	5	5	90	Follow USPSTF guidelines	5	5	90	0	0	0	1 in 5 cases of cervical dysplasia/cancer will be missed by HPV only
CA	10	0	90	ASCCP recommendations	0	0	100	-10	0	10	I follow ACOG.
NY	10	0	90	Pap only under 30	10	0	90	0	0	0	Would go by ACOG
CA	15	0	85	We do age based screening	15	0	85	0	0	0	Not all cervical cancer is caused by HPV
CA	20	0	80	Cotest if 30 or above, pap only with reflex if 21-29	20	0	80	0	0	0	Unless our company changes guidelines, we will continue cotesting if > 30
GA	20	0	80	Don't perform HPV primary testing.	20	0	80	0	0	0	I don't believe in HPV primary testing. it is not "primetime."
IL	20	0	80	HPV primary is still not standard of care. I have done co testing for many years.	10	33	57	-10	33	-23	I am cognizant of USPSTF, but have a comfort level with what has worked for years.
NY	20	0	80	Any woman 21-29 I do pap only, 30 and above perform co-testing	20	0	80	0	0	0	I wouldn't change unless ACOG states this is the new way
CA	25	0	75	I follow the ASCCP guidelines with pap testing for < 30 yo and cotesting for all > 30	0	100	0	-25	100	-75	I agree that HPV testing is the most important screen
NY	25	0	75	ASCCP guidelines with age adjustments. Often patient prefers cytology over HPV a	25	25	50	0	25	-25	I would still want cytology particularly if longstanding history of HPV+ status.
IL	0	30	70	Our practice just started primary HPV for everyone.	0	80	20	0	50	-50	There are patients with previous abnormal or S/P colposcopy where cytology is helpful.
NC	30	0	70	We do not have the capability for primary HPV testing in my office	30	0	70	0	0	0	I am not sure what it would take to convince our lab to offer primary HPV testing
NY	35	0	65	I do pap only for pts under the age of 30 and pap+HPV for pts over the age of 30	35	0	65	0	0	0	Unless ACOG, ASCCP or SGOG changed recommendations, I would not offer HPV pri
MA	0	45	55	Based on current guidelines and patient preference	0	85	15	0	40	-40	Based on patient preference
NV	50	0	50	ASCCP guidelines and prefer co testing to HPV as it allows for cervical cell evaluat	30	20	50	-20	20	0	Again would depend on the patient, their prior pap history, their compliance, etc
VA	50	0	50	I don't order HPV dna alone	50	0	50	0	0	0	I did not change, patients prefer to do Pap test
FL	30	30	40	HPV testing is the future	0	60	40	-30	30	0	HPV is the future
NY	30	30	40	Co testing is best	10	10	80	-20	-20	40	Co testing is best
FL	20	50	30	Try to follow GYN Onc guidelines	10	60	30	-10	10	0	See above
FL	75	0	25	Estimated	65	10	25	-10	10	0	Estimated
NY	60	20	20	Some patient ask for primary HPV or co-testing. I still recommend cytologic screeni	20	60	20	-40	40	0	I would start recommending HPV primary testing if USPSTF recommended over Pap
IL	20	70	10	I primarily order HPV testing..	0	100	0	-20	30	-10	If USPSTF recommends only HPV primary, then I intend to follow these guidelines.
FL	0	100	0	N/A	0	100	0	0	0	0	N/A
CA	20	80	0	Follow guidelines	10	30	60	-10	-50	60	Will follow guidelines to a large extent

Source: Nephron Research

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