

DELIVERING CANCER DIAGNOSTICS TOOLS

With regulatory changes anticipated but not yet articulated, it's hard to know the best path forward for companies developing cancer diagnostics-related tools and tests.

BY MARK L. RATNER

- The opportunity to deliver new cancer diagnostics tools is of great interest to many stakeholders including pharmas, diversified diagnostic testing laboratories, and instrument/reagent companies, as evidenced by a spate of acquisitions of specialty cancer labs.
- However, these tests are more complex than traditional diagnostics, and the CLIA lab model many companies have espoused for delivering them has significant limitations including a lack of experience creating kits for regulatory approval and global distribution.
- On the other hand, a CLIA lab that focuses on anatomic pathology dovetails nicely with imaging and radiology, and is therefore a logical nexus for technology aggregation. CLIA labs are also a warehouse of diagnostics development talent, making them a convergence point for drug-diagnostics co-development.
- That said, such acquisitions may only make sense if they are also seen as sustainable commercial operations in their own right. Questions around the degree and kind of leverage owning a CLIA lab provides evoke many of the larger issues around commercialization of complex diagnostics tests.

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As Yogi Berra famously said, “When you come to a fork in the road, take it.” The Hall of Fame New York Yankees catcher may well be advising the health care industry these days, because when it comes to the new wave of cancer diagnostics, it seems to be just what is happening. Pharma is keenly interested in these tools, which in many cases are aimed at selecting the best therapy for a specific patient, measuring response to therapy and predicting or more sensitively measuring relapse. So are payors. But deciding with whom and how to ally for the development and distribution of these tests is difficult, showing just how uncharted – and bumpy – is the current diagnostics terrain.

Genomic Health Inc. was on the leading edge of this diagnostics wave, with its *Oncotype Dx* test for predicting response to chemotherapy in breast cancer. Specialty labs like **Genoptix Inc.**, which **Novartis AG** bought this year, and **Clariant Inc.**, an acquisition target of the **GE Healthcare** division of **General Electric Co.** in 2010, are acquiring test IP and performing highly specialized services for community oncologists. And a host of small companies are developing new technologies including advanced flow cytometry and more sensitive protein analytics, circulating tumor cell extraction and next-generation sequencing, which can all contribute to the assessment of cancer patients.

Because the use of these diagnostic methodologies will presumably greatly enhance medical decision-making, they are drawing the interest of regulators: the US Food and Drug Administration has stated its intention to review complex tests that

have long been the province (at least in the US geography) of specialty labs regulated under CLIA, and performed only in those labs. That will mean generating the kind of evidence not traditionally required of the diagnostics industry – as **Genomic Health** has done, albeit to satisfy payors not FDA, as well as to drive adoption among oncologists. And because these tests and tools are far more complex than traditional diagnostics in terms of what they measure and how they interpret those measurements to be able to guide therapy of individual patients, it’ll take time and a lot of patients in clinical trials to build the requisite evidence to present to FDA for review. Both those factors increase the test development costs, which in turn add to the investment risk for diagnostics content developers and their backers.

Which leads us to pharma’s fork in the road: what path to take to assure development – and importantly, global distribution – of the diagnostics it knows it will need to support the launch of new targeted drugs? Can a geographically fixed specialty lab operating under CLIA regulations suffice? Is it better to partner with dedicated diagnostics developers such as **Roche** or **Abbott Laboratories Inc.** on a test-by-test basis, or is there a need for more captive in-house diagnostics expertise to assure the best decision-making in terms of which test to bring forward into commercial development, when, and using which assay platform?

No doubt, there will be multiple business models to address these new and critical issues, depending on a company’s structure and the needs of an individual drug development program. And as we wrote in

IN VIVO in April 2011, there's been a definite uptick in dealmaking around diagnostics, driven by an array of new and traditional participants with a varied set of interests and capabilities. (See "What's Fueling The Recent Diagnostics Dealmaking?," IN VIVO, April 2011.) In many cases, these new partners, which include large diagnostic testing labs and instrument/reagent providers, give young companies an enhanced conduit into pharma because of what they themselves offer drugmakers – an aggregation of capabilities beyond test content, often as part of an existing, dedicated, clinical trials service business. Or in the case of a pharma acquirer, it may be a way for the pharma to build out a more complete health care offering by deepening its marketing and sales channel to include diagnostics, or because it is interested in diversification and sees diagnostics as a valuable business in its own right.

A MORE COMPLEX BIOLOGY

Developing predictive markers for complex medical actions like telling a physician when to administer a therapeutic demands the identification of much more complex biology than that required for traditional diagnostic tests, says David Parkinson, CEO of **Nodality Inc.** "If you can more effectively identify patients whose underlying biology makes them contextually relevant for a particular therapeutic, all of a sudden you have a more efficient test system and can dissect the contribution of a drug," he says, and in so doing determine if a drug is necessary – and even more important, not sufficient – for successful therapy. That's the goal of Nodality, which is focused on developing highly predictive tests to better inform clinical treatment decisions in cancer and autoimmune diseases by characterizing the functional status of signaling networks at the single-cell level.

Biomarker Strategies LLC, another start-up company, is similarly looking at the signal transduction circuitry of the cell, the bypass mechanisms and the resistance mechanisms present within it, and the biomarker readouts – namely, the newly evoked phosphoproteins in various drug pathways – that will be markers of drug effect. "The target of targeted therapies is really the entire signal transduction network," says Acting CEO and Chief Medical Officer Douglas Clark, MD. "We need better tools to understand how we are influencing that."

The approaches taken by Nodality and Biomarker Strategies illustrate the complexity of predictive biomarker discovery aimed at drug selection and monitoring. If one looks at DNA analysis alone, there are only a small number of mutations that are quite predictive, Clark says. "We know the cast of characters: EGFR mutations, KRAS mutations, etc. While we think that landscape will continue to have some relevance, the vast majority of tumors are either not going to have those mutations or we are not going to be able to predict targeted therapy sensitivity and resistance based on them." In other words, more times than not the signaling is more complex. Nodality, for example, has shown that the class of drugs known as FLT3 inhibitors doesn't always work on cells with FLT3 mutations because the growth and spread of half of those cells are not governed by the FLT3 pathway.

Unlike Nodality, Biomarker Strategies is focused on solid tumors, which adds still another level of complexity to the diagnostic problem: getting a live tumor sample for analysis. "Flow cytometry is a good platform to perform immunophenotyping and other complex analyses on leukemia and lymphoma, such as those done by Nodality," Clark says. But solid tumors present a lot more challenges in general for molecular diagnostics – specifically for live cell analysis. The cells are cohesive, so they come

out in aggregates that are difficult to disperse and work with. They also are heterogeneous, containing variable amounts of contaminating cells – lymphocytes and macrophages. Biomarker Strategies' *SnapPath* processing device disperses biopsy samples, including those taken using fine needle aspiration (FNA), into small aggregates that can be easily manipulated within the device. It then enriches the live cell suspension by removing contaminating lymphocytes and macrophages. That leaves the tumor sample set up for ex vivo stimulation by growth factors and other substances that activate the signal transduction network. As a result, the cells can be studied in the presence of a drug or an inhibitor of one of those pathways, and biomarkers for those processes identified.

"We are in the process of validating our functional signaling profile and are in the process of shoring up the intellectual property around that," says Clark. "We are finding information that identifies intrinsic bypass mechanisms that would, for example, enable you to predict which targeted agents are, or are not, effective." Knowing the bypass mechanisms for single agents also helps determine which combination therapies may be effective.

As the firm's name implies, biomarker discovery is its underlying mission. Still, the importance of having an automated, live sample processing technique should not be undervalued; indeed, a common element of many of the new diagnostics tools is that they provide access to malignant cells in a state that better mirrors the actual biology of the tumor of interest, versus preserved biopsies taken early on and only once in the course of treatment. "We are trying to sample the tumor more often, with minimally invasive FNAs, to stay one step ahead of the resistance that invariably will emerge in these patients," such as that seen with the new BRAF inhibitors in melanoma, says Clark. Continued biopsy by conventional methods is a nonstarter.

Another alternative would be to collect circulating tumor cells (CTCs) in blood – the goal of start-up **On-Q-ity Inc.** as well as **Johnson & Johnson's Veridex LLC**, which has been marketing a kit for counting rare tumor cells since 2004 and recently engaged in a collaboration with **Massachusetts General Hospital** to evolve its technology to be able to analyze as well as enumerate CTCs. (See "J&J Snaps Up Rare Cell Capture And Analysis Technology From Mass General," IN VIVO, January 2011 and "On-Q-ity Inc.," START-UP, January 2010.) But even a captured and intact CTC may not represent the clonal population of bad actors that evolve into the metastatic disease that ultimately kills the patient, as opposed to cells that respond to first-round chemo. Or, a CTC may be "artificial" in other ways because, for example, it has been stimulated by receptor engagement during the capture process.

Sequencing instrument provider **Illumina Inc.** has a skunk works program in CTCs. "We've got some proprietary technology that improves the signal-to-noise ratio," says Greg Heath, PhD, SVP and general manager of the company's diagnostics business unit. "That allows us to capture intact cells we can then interrogate with some of our other technologies. Depending on the yield, you can run an array against them or input into a sequencer. Then you can fully characterize those cells." Of course, obtaining that sufficient yield has been a stumbling block for the field.

CTCs and other tumor sample acquisition technologies could provide a much improved substrate for sequencing analysis. And although the availability of faster and cheaper sequencing may one day provide routine diagnostic information, there's an active debate about the level of information needed, especially when looking at a series of small variants in many genes. (See "The How

And When Of Applying Sequencing To Clinical Diagnostics," IN VIVO, September 2010.) It's another example of the complexity facing diagnostics developers and regulators, and pharma is not about to bet the success of a targeted drug on a complex assay that FDA is years away from being able to grasp.

"One of the misconceptions about next-generation sequencing is that just because it's cheaper to get the data, that it's telling you something useful," says Steven Little, VP, personalized healthcare at **Qiagen NV**. To understand what the data mean entails seeing it enough times to be able to understand the relationship between a change and a clinical response. That's where the big expense comes in, he says, in time and trials. "Next-gen sequencing is a tremendous tool for discovering biomarkers, but I do not see it as a way of moving diagnostics into the marketplace in the short term. Certainly not in the regulated end of the marketplace," he says.

That's not to say such technology isn't useful in an R&D context. There it's "quite valid," says Little, who was co-founder and CEO of DxS, a developer of tests for KRAS and EGFR cancer mutations, which Qiagen acquired in 2009. As a result, it's not surprising that pharma is actively contracting for sequencing services, largely for the analysis of the impact of changes in a single gene or a very small set of genes across different tumor types. But as Little implies, given the regulatory hurdles, next-generation sequencing seems destined to remain mainly a research service, not a platform for commercial diagnostics, for the next several years at least.

It's understandable that when it comes to incorporating diagnostics technology, pharma takes a conservative approach. Chris Chamberlain, medical director for personalized medicine at **AstraZeneca PLC**, emphasizes that his firm seeks technologies that are "fit for a purpose" and can be validated as such. "We have a watching brief on new technology, but of course what is critical in this space is that something needs to be translatable into pathology practice. We're talking about biomarker concepts that need to go all the way to the patient, so consequently our focus is on mature technology that has proven diagnostic potential."

For tools developers, that still means often turning to the traditional route of driving adoption in the unregulated "Research Use Only" setting, first. For that, they are seeking out partners with existing access to pharma, via research or clinical trials. And there is a range of partners to consider.

"One of the big problems we have is that not all of the markers we need can be reduced to a single assay," says Nicholas Dracopoli, PhD, VP, biomarkers, for **Ortho Biotech Oncology Research & Development**, a J&J business unit. "No single technology will give us the clinical readouts we need." Nor can any one company offer the expertise to address all the facets of clinical diagnostic development. "There's no one company, even a company as big as Roche Molecular, that is able to offer everything from pathology services all the way through to molecular or protein analysis," he says. "It's on the end user developing the assay around the drug to figure that out." Dracopoli also acknowledges that his group is having internal discussions around extending its internal CLIA expertise. "It's being explored, yes. And CLIA services are already offered for CTCs as part of the services business of Veridex."

POSSIBLE MODELS FOR CONTENT COMPANIES

Drug makers may want to test multiple instrumentation platforms for biomarker discovery and development and require regulatory diagnostic expertise and global distribution aligned with a drug launch. The need for those capabilities is driving much of

the recent dealmaking for CLIA facilities. For diagnostic test and technology providers, partnering with those acquirers and their ilk may therefore provide an enhanced conduit into pharma in several ways, because they often already have services to offer pharma in addition to test content.

In cancer, it's particularly important to work with a partner that already has access to or control of the clinical sample, to maintain the workflow in a central location. Thus, companies are gravitating toward partners that already control the clinical sample by providing anatomic pathology services. It is a capability that labs possess, as do the pharma/diagnostics conglomerates including Roche, Abbott, and now Novartis, as well as other entities (GE, for example) that see the value of laboratory services.

New diagnostics tools may also work well alongside of in vivo imaging. About half of the revenue in diagnostics over all comes from imaging – CT scans, MRIs, PET, ultrasound. Those technologies are very good for providing anatomic localization of tumors. However, imaging doesn't necessarily provide data at the molecular level. Thus, it's a natural extension for an imaging equipment manufacturer like GE to integrate into immunohistochemistry by buying Clariant, to vertically integrate the oncology channel. And because large capital equipment companies are well versed in the services side, it gives them a comfortable early entry into that space. (See "GE Acquires Clariant To Anchor Its Molecular IVD Business," IN VIVO, December 2010.)

In some respects, the rationale underlying GE/Clariant is similar to that of **Siemens AG's** acquisition of Bayer Diagnostics – to link up in vivo imaging and IVD. It's part of a new paradigm where patient management decisions are made jointly by the treating clinical pathology group, the anatomic pathology group, and the radiologist, says Dave Okrongly, CEO of **Quanterix Corp.**, which is developing methods for more sensitive protein analysis. Okrongly was head of R&D for Bayer Diagnostics and continued to run it for two years under the Siemens' umbrella. With Clariant, "GE is trying to put together in vivo and in vitro by focusing on anatomic pathology," he says. "A CLIA lab that primarily does anatomic pathology is probably getting the directional correctness on how to bridge the gap between what's traditionally done in clinical diagnostics and what's done in imaging and radiology." One can see the same thing at work with Roche's signature 2007 acquisition of **Ventana Medical Systems Inc.**, or in Qiagen's stated but as yet unfulfilled interest in digital pathology. (See "Taking Stock Of Qiagen," IN VIVO, November 2010.)

But interestingly, Okrongly decided last year that Quanterix would be leaving a lot on the table if it were to pursue the CLIA lab model, which had been its aim. (See "Quanterix Corp.," START-UP, July 2010.) "We realized if we go the CLIA route, and let's say we develop the next greatest way to predict who's going to recur with prostate cancer, or the next best way to identify patients with early signs of Alzheimer's who should be getting therapy, that we would then become a very focused company along the lines of Genomic Health," he says. Instead, the vision is now to broaden Quanterix's reach by offering the technology platform to the life science research market and relying on its users to identify IVDs for Quanterix to develop. (To that end, it has seeded its technology within Novartis under a 2011 collaboration with the latter's blood screening group in Emeryville, CA. While Okrongly would not comment on Novartis' strategy, he did say that "their business interests and ours seem poised for alignment down the road.")

By comparison, On-Q-ity, for its part, has both established a distribution relationship with **Laboratory Corp. of America Hold-**

ings for the research market and is in parallel anticipating its own CLIA lab, to use for samples from pharma partners and ultimately for clinical readout. (For more on how-tos of leveraging platforms into clinical applications, see “Leveraging Assay Platforms to Create Category-killer Diagnostic Tests,” IN VIVO, December 2009.)

TO KIT OR NOT TO KIT: REGULATORY AND DISTRIBUTION CONCERNS

Instead of a diagnostics world in which tests could be commercialized as long as they met test performance characteristics and were performed in a single CLIA lab, now, a test that starts to make clinical claims – that it is more predictive, more prognostic, such that there’s a significant chance that it affects clinical decision-making – is going to be reviewed by FDA. “It’s much less clear that tests can immediately be brought out by a single lab, under CLIA, for commercial purposes,” says Nodality’s Parkinson.

“Regulators have identified this as very important in a space where they’ve always had authority but have never used enforcement discretion,” he points out. Now, they’ve used their discretion to declare they want to regulate this area, “without frankly a lot of internal skill sets to evaluate the technologies,” he says. So all of a sudden, the diagnostics industry is looking at a world where all sorts of predictive tests probably cannot be routinely developed and released under CLIA but increasingly will be regulated by FDA, with all the uncertainties of time, resources, and likelihood of success that entails due to increased regulatory expectations for higher levels of clinical evidence. That is increasing the time, rigor, and cost of development of a predictive clinical test, which has molecular diagnostics companies looking at a longer time

to commercial success. Plus, although a lab such as Clariant or Genoptix could conceivably build a test and get it approved by FDA, that capability is not part of their core services business.

In the meantime, there’s been no change on the reimbursement side to act as an incentive: even as more complex tests are being developed, under current CPT codes, the approach is often to use stacked CPT codes and other tactics to up reimbursement. But it’s clear that with tighter regulation, those tactics are on the way out, leaving the hope that new reimbursement systems will better reflect the clinical value and increased time and rigor required in developing the new generation of more highly predictive and more prognostic diagnostic tests.

“So you’ve got a group of molecular diagnostics companies that’s challenged right now,” says Parkinson, referring to sustainability of the classic model of developing a test that’s perceived to have some value and then proceeding to commercialize it. There’s also a level of mistrust of the diagnostics industry within some pharma circles, given circumstances like the variability of Her2 testing in breast cancer. (See “Her2 Testing: What’s Old is New,” IN VIVO, December 2008.) Even simple things such as test tubes being switched occur uncomfortably often, the head of **Novartis Molecular Diagnostics**, Michael Nohaile, PhD, told a gathering of reporters in May when discussing the rationale for Novartis’s decision to make molecular diagnostics acquisitions.

Into all of this opportunity and great challenge come some new players. And those players enter from different worlds. There’s Big Pharma, instrument and reagent players, and the big diagnostic lab players, with Labcorp and **Quest Diagnostics Inc.** as specific examples of the latter. (See Exhibit 1.) That’s at least

Exhibit 1

Recent Acquisitions Of Specialty Service Labs

ACQUIRER/ASSET ACQUIRED (DATE)	PRICE (\$ MILLIONS)	COMMENTS
Myriad Genetics/Rules-based Medicine (April 2011)	80	Biomarker testing services using a proprietary immunoassay platform for preclinical and clinical development.
Quest Diagnostics/Celera (March 2011)	671	Assets include Celera’s Berkeley HeartLab and proprietary cardiovascular tests performed there, as well as a biomarker pipeline. Access to Quest’s patient service centers to perform phlebotomies expected to drive uptake of Celera’s <i>kif6</i> test for identifying people at risk who may benefit from taking a statin.
Quest/Athena Diagnostics (February 2011)	740	Former parent Thermo Fisher Scientific divested Athena, a reference lab for development of diagnostic tests for neurological disorders, as well as its other lab testing service operations.
Novartis/Genoptix (January 2011)	440	Provider of personalized cancer testing services, largely in hematology-oncology, to community oncologists. Acquired for a 1.7x multiple of trailing 12 month revenues.
GE/Clariant (October 2010)	587	GE aims to make Clariant, a provider of cancer testing services, the cornerstone around which it builds a molecular IVD business.
Labcorp/Genzyme Genetics (September 2010)	925	Genzyme divested this nine-lab network focused on maternal serum and genetic carrier screening, pre- and postnatal diagnostics, and clinical trials services as part of the company’s positioning to be acquired. Allows Labcorp to expand its offerings in reproductive, genetic, and cancer testing.
PerkinElmer/Signature Genomic Laboratories (April 2010)	90	Acquisition of this microarray-based service lab strengthens PerkinElmer’s prenatal diagnostics and cancer testing capabilities.

SOURCE: Elsevier’s *Strategic Transactions*

three different kinds of parties looking at the promise of the new molecular diagnostics, trying to figure out what it means to their businesses. And it means something different for each stakeholder. Novartis, for example, clearly appreciates the value of a clinical laboratory service business like Genoptix's, which goes directly to the community oncologists (who comprise upwards of 70% of all the hematologist-oncologists in the US), bypassing the local hospital pathologist. (See "With Genoptix, Novartis Continues Its Diagnostics Build-up," *IN VIVO*, February 2011.) Quest Diagnostics acquired **Celera Corp.** in part because Quest's array of patient service centers can perform phlebotomies, which should, better than Celera's lone **Berkeley HeartLab Inc.** facility, drive uptake of Celera's *kif6* test for identifying people at risk for cardiovascular disease who may benefit from taking a statin. Instrument/reagent companies similarly appreciate the service model, and figure they can position themselves well in the new, biology-driven diagnostics world. And pharma, quite simply, needs to know there's a commercial test infrastructure in place to go along with the marketing of its targeted drugs.

Moreover, there's potentially going to be a value shift toward the value of diagnostics in the context of the use of therapeutics, says Parkinson. "The relative values will shift as we move to a world where many of the important targets are addressed by generics or follow-ons and the use of the tests may well be gated by more expensive and more clinically valuable diagnostics. I think there's every reason to believe that the relative valuations of drugs and diagnostics will go from 95%-5% on the drug side toward something different."

Of course, that's fine talk, but in reporting done for this story and others, we've yet to uncover any firm evidence of it happening. On the other hand, while payors are pushing back on high prices for oncology drugs, those drugs that are tied to specific companion diagnostics and that show better evidence for their utility in a defined patient population are being put on "pathways" – pilot programs by payors aimed at establishing a standard of care. (See "What New Cancer Pathway Programs Mean For The Drug Industry," *IN VIVO*, May 2011.)

In that sense, Novartis may be more forward looking – certainly more aggressive. "Most Big Pharma companies don't appear to have a broad strategy to integrate the new diagnostics into their business model," says Parkinson. Although they are always talking about biomarkers and personalized medicine, "they're really talking about them as tools for drug development," he says. "As opposed to recognizing that's actually the future of clinical medicine, where the use of these advanced personal diagnostics is integrally linked with the therapeutics."

PHARMA RX-DX CO-DEVELOPMENT OPTIONS/STRATEGIES

Largely because of anticipated regulatory changes aimed at getting a handle on tests developed around complex biology, it's a new world in diagnostics, with more stringent requirements and longer timelines, affecting both test and technology developers and also, at some point, pharmas, which are coming to appreciate the need to have companion diagnostics at the ready to be able to sell their drugs.

The Clariant and Genoptix deals, and the fact that several drug-makers apparently were engaged in the bidding for each, evidences pharma's awareness that there are precious few channels to make advanced diagnostics tools available to support a big launch of a new drug. But sales and marketing synergies within the pharma

conglomerates are limited. For Novartis, for example, even with the obvious companion diagnostics fit between the hematology-oncology services Genoptix offers and Novartis' portfolio of targeted leukemia drugs, there's an absolute wall between Genoptix's operations and the marketing activities of Novartis Molecular Diagnostics, according to Nohaile. And while having a CLIA lab can in some measure bring a manufacturer closer to customers because they sell their products to labs and labs sell tests to doctor, the channel synergies are limited: they could provide a better insight into doctors, but at the risk of losing the focus on selling to labs.

On the other hand, the competitive bidding and prices paid also show that for some companies – even a pharma used to much higher margins – specialty labs are an interesting business in and of themselves as vanguard service opportunities in cancer care. In Novartis' case, it's unlikely it would have bought Genoptix solely for its utility in biomarker R&D, with potential partners like Roche and Abbott willing and available to do the same work. (**Pfizer Inc.**, for example, retained Abbott's **Abbott Molecular Inc.** division to develop a companion diagnostic for its lung cancer drug crizotinib, now before FDA. **GlaxoSmithKline PLC** has twice turned to Abbott for companion diagnostics for its Mage-A3 immunotherapies. And earlier this month **Merck & Co. Inc.** inked a deal with Roche for the latter to develop assays for Merck's investigational cancer drugs.)

If one presumes an eventual realignment of the relative value of a drug-diagnostic combination more toward the diagnostic, some drug companies may well prefer to own the channel instead of going to a large lab network such as Quest or Labcorp, which are each building significant clinical trials services channels both nationwide and ex-US that could be used to determine which patients should be on which therapy. But the uncertainties around getting paid for the task of developing molecular diagnostics – and importantly, having the means to distribute them – remain. Pharmas are barely amenable to even considering a risk-sharing arrangement, and apart from the stakes in the ground being set by Novartis, there's little to indicate movement in pharma toward direct support of diagnostics development, as opposed to the case-by-case use of service providers for commercializing companion diagnostics.

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