



Competitive Bidding Program for Mail-  
Order Diabetes Testing Supplies:  
Product Availability Survey

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## EXECUTIVE SUMMARY

Diabetes testing systems and supplies are the cornerstone of patient self-management. The quality and accuracy of these systems and supplies, and a person with diabetes ability to effectively and appropriately use them are critical to supporting titration of insulin and calibration of other self-management devices. Access to systems recommended by the healthcare professional are decided with the patient to optimize success of therapy and clinical outcomes. Systems and supplies are selected based on the patient's individual needs.

Since implementation of the competitive bidding program (CBP) for diabetes testing supplies (DTS) purchased through mail-order suppliers in January 2011, reports have repeatedly surfaced suggesting that product choices are limited and that beneficiaries may not have access to the full range of products that were available before the program began. In 2011 and again in 2013, the American Association of Diabetes Educators (AADE) conducted studies to evaluate the extent to which Medicare's contract suppliers offered and made available different brands and models of DTS. In those studies, diabetes educators surveyed contract suppliers authorized to sell DTS to Medicare beneficiaries through mail order to determine which products each supplier offered and made available, and compared that information with the information available in the Medicare supplier database.

Through these studies, AADE found the following:

- Contract suppliers in Round 1 and in the initial National Mail-Order (NMO) program did not make available all of the products that were listed on the Medicare.gov Supplier Directory (MSD); and
- Many of the products available to Medicare beneficiaries before implementation of Round 1 were no longer available through NMO suppliers.

The Centers for Medicare and Medicaid Services (CMS) is required to recompete all DME CBP contracts at least every three years. In 2016, CMS implemented the NMO recompetite, the first full recompetition for nationwide mail-order suppliers of DTS. Suppliers participating in the NMO recompetite agree to provide DTS to Medicare beneficiaries in all parts of the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.

AADE conducted this third study to further examine the range of DTS offered by contract suppliers to Medicare beneficiaries. In light of the results, AADE remains concerned that the CBP is harming persons with diabetes by limiting access to and choice of DTS. If beneficiaries have difficulty finding replacements for familiar products, they may be inappropriately influenced to switch DTS. Product switching can have negative health and economic consequences. When a beneficiary is forced to switch to unsuitable, unknown, confusing, or unreliable DTS, testing compliance may diminish or even cease. Poor blood glucose management can increase the risk of

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complications such as blindness, kidney damage, cardiovascular disease, and lower-limb amputations.

In this study, five diabetes educators contacted 11 suppliers<sup>1</sup> and found the following:

- The number of brands of DTS carried by NMO suppliers has fallen nearly 50 percent since the start of the CBP;
- The number of models of DTS available under NMO is less than half the number available in 2009;
- Many suppliers do not offer models covering 50 percent of the market share of DTS; and
- Suppliers do not provide consistent information about inventory to prospective customers.

These findings demonstrate that as a result of the CBP, Medicare beneficiaries have fewer choices and limited access to the DTS most commonly used before implementation of the CBP. As a result, beneficiaries who chose to obtain their DTS through mail-order suppliers are effectively being made to either switch to different DTS or purchase DTS through non-mail-order settings. As previously noted, switching to unfamiliar or unsuitable DTS can carry health consequences. This study also demonstrates that the information available from suppliers themselves is inconsistent and may be further complicating Medicare beneficiary's ability to find appropriate DTS.

Despite these troubling findings, AADE did see some improvement. In previous studies, AADE found that information on Medicare's website about which DTS suppliers offered often was inaccurate, further contributing to beneficiary confusion and frustration. In this study, we found fewer instances of discrepancies between the information provided on Medicare.gov and the reality of DTS made available by contract suppliers. The AADE commends CMS for improving the accuracy of its website.

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<sup>1</sup> Appendix A includes a list of 11 suppliers contacted for this survey.

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## **ABOUT THE AMERICAN ASSOCIATION OF DIABETES EDUCATORS**

The American Association of Diabetes Educators (AADE) is a multi-disciplinary professional membership organization dedicated to improving diabetes care through innovative education, management and support. With more than 14,000 professional members including nurses, dietitians, pharmacists, exercise specialists, and others, AADE has a vast network of practitioners working with people who have, are affected by or are at risk for diabetes. The AADE's mission is to empower diabetes educators to expand the horizons of innovative education, management and support and to ensure optimal health and quality of life for persons with, affected by or at risk for diabetes and chronic conditions.

Diabetes educators are healthcare professionals who focus on helping people with diabetes understand their disease and learn how to adjust their lifestyle and behavior so that they can develop diabetes self-management skills.

## **BACKGROUND**

It is well understood that diabetes presents a significant and growing public health concern. Uncontrolled diabetes leads to significant complications including cardiovascular disease, nerve damage, loss of vision, kidney damage and more. Self-monitoring of blood glucose (SMBG) levels provides an important tool that can provide immediate feedback to patients about the effects of food choices, activity and medication.<sup>2</sup>

On January 1, 2011 CMS implemented the CBP for certain items of Durable Medical Equipment and Supplies in nine geographic areas. Diabetes testing supplies (DTS), such as blood glucose testing strips used for SMBG, purchased through mail order, were one of the initial product categories subject to the CBP.

In 2012, CMS, through the NMO competition, expanded the scope of the CBP for DTS to include the entire nation, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Beginning July 1, 2013, any Medicare beneficiary wishing to purchase DTS via a mail-order supplier was required to use one of 20 winning contract suppliers. Beneficiaries choosing to purchase their supplies from a “brick and mortar” DME storefront or pharmacy could continue to do so at any Medicare-certified supplier.

On July 1, 2016, CMS implemented the NMO recompetes, the first full recompetition of contracts to supply DTS nationwide through mail order. The NMO recompetes also covers beneficiaries in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Under the NMO recompetes, CMS awarded contracts to 11 winning suppliers. Since the initial award of contracts, two suppliers, Arriva Medical and US Health Care, left the program and were replaced by All American Medical Supplies and

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<sup>2</sup> Dailey G. Assessing glycemic control with self-monitoring of blood glucose and hemoglobin A(1c) measurements. *Mayo Clin Proc.* 2007;82(2):229–235.

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Medenvios Healthcare. We note that only four of the 11 winning contract suppliers under the NMO recompetes served as winning suppliers under the first round of the NMO program. Appendices A and B to this report list the suppliers awarded contracts under the NMO recompetes and the first round of the NMO program respectively.

As with the initial NMO competition, Medicare beneficiaries wishing to purchase DTS via a mail-order supplier must do so through one of the 11 winning contract suppliers. Beneficiaries choosing to purchase their supplies from a “brick and mortar” DME storefront or pharmacy can continue to do so at any Medicare-certified supplier.

Since implementation of the CBP, there have been anecdotal reports of beneficiaries having limited choice of products, misleading advertising by the contract suppliers, inaccurate information on Medicare’s website, and abusive practices by contract suppliers actively trying to switch beneficiaries to different testing systems.

To investigate these reports, AADE conducted a study in November 2011.<sup>3</sup> In that study, diabetes educators surveyed contract suppliers – *i.e.*, suppliers authorized by CMS to furnish DTS via mail order to Medicare beneficiaries in the nine Competitive Bidding Areas – to determine the range of products offered and the accuracy of information supplied by CMS via its website, Medicare.gov. AADE found of the nine brands that the Inspector General for the U.S. Department of Health and Human Services identified in a December 2010 report as the top mail-order DTS brands by percent of market share, contract suppliers offered on average only 16 percent.<sup>4</sup> AADE further found that contract suppliers, on average, offered only 38 percent of the products said to be offered on Medicare.gov.

In light of the expanded CBP for DTS in 2013, AADE repeated its study.<sup>5</sup> AADE sought to once again examine the range of products available to Medicare beneficiaries and the accuracy of information provided to beneficiaries by Medicare. AADE also evaluated whether the statutory provision that requires suppliers’ bids to represent at least 50 percent of all types of DTS by volume had any impact on the mix of products available from NMO suppliers.<sup>6</sup>

The second study confirmed AADE's initial findings of disruption to access. Specifically, the second study showed that only five of the 20 NMO suppliers offered more than 50 percent of the test systems available to beneficiaries before

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<sup>3</sup> "Competitive Bidding Program for Mail-Order Diabetes Testing Suppliers: Product Availability Survey." American Association of Diabetes Educators, 17 Nov. 2011. [https://www.diabeteseducator.org/docs/default-source/default-document-library/aade\\_dme\\_survey\\_2011.pdf](https://www.diabeteseducator.org/docs/default-source/default-document-library/aade_dme_survey_2011.pdf). Last Accessed 12 Dec. 2016.

<sup>4</sup> HHS Office of Inspector General. *Medicare Market Shares of Mail Order Diabetic Testing Strips (OEI-04-10-00130; 12/10)* Dec. 2010. <https://oig.hhs.gov/oei/reports/oei-04-10-00130.pdf>. Last accessed 12 Dec. 2016.

<sup>5</sup> "Competitive Bidding Program for Mail-Order Diabetes Testing Suppliers: Product Availability Survey." American Association of Diabetes Educators, 2 January 2014. [https://www.diabeteseducator.org/docs/default-source/legacy-docs/resources/advocacy/aade\\_study\\_on\\_suppliers\\_2014.pdf](https://www.diabeteseducator.org/docs/default-source/legacy-docs/resources/advocacy/aade_study_on_suppliers_2014.pdf). Last accessed 12 Dec. 2016.

<sup>6</sup> Soc. Sec. Act 1847(b)(10)(A).

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implementation of the CBP. The study also showed that Medicare's supplier database contained accurate information on the available inventories of only three suppliers. Furthermore, the second study demonstrated that when a supplier is queried on different occasions about the test systems they carry, the information provided is inconsistent and unreliable. In only a very few occasions were all surveyors given consistent responses about the brands available.

## OBJECTIVE

This is the third in a series of studies performed by the AADE designed to assess the impact of the DME Competitive Bidding program on beneficiary access to diabetes blood glucose test systems. This study is focused on the impact of the National Mail-Order recompetete.

## METHODOLOGY

As with the previous studies, five diabetes educators surveyed contract suppliers listed on the [www.medicare.gov](http://www.medicare.gov) website as of November 7, 2016; 130 days after the contracts under the NMO recompetete were awarded.<sup>7</sup> Surveys were conducted during the period November 8, 2016 through November 18, 2016. Surveyors were furnished with a list of contract suppliers and contact information. The list of suppliers surveyed may be found at Appendix A to this report.

Using the MSD, beneficiaries can identify contract suppliers authorized to furnish DTS by mail order, and identify the products purported to be offered by and available through each of the suppliers.<sup>8</sup> On November 7, 2016, we identified the specific brands and models available from each NMO supplier as reported by CMS using the MSD. This listing was the baseline against which the surveyors compared the test systems actually available to program beneficiaries.

Each supplier was contacted by five different surveyors. For each survey, the surveyor contacted the contract supplier, identified himself/herself as a diabetes educator, and inquired about the availability of the blood glucose test supplies listed as being offered on Medicare.gov. If the supplier confirmed that the product was available to be furnished to a beneficiary, the surveyor noted that on the survey. If the supplier

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<sup>7</sup> On July 1, 2016, CMS awarded National Mail-Order contracts to 11 DME suppliers. Subsequent to the award, but prior to commencing this survey, Arriva and US Healthcare left the NMO program. Prior to the beginning of this survey, CMS awarded replacement contracts to Medenvios Healthcare and All American Medical Supplies. We note that with this change in suppliers, only four of the 11 suppliers had been awarded a contract under previous rounds of the National Mail-Order program. The AADE is concerned that the changing contractor landscape combined with the lack of experienced contractors under the NMO program may be contributing to beneficiary confusion and forcing beneficiaries to change testing systems.

<sup>8</sup> The Medicare Supplier Director is available at <https://www.medicare.gov/supplierdirectory/search.html>.

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reported that the product was not available, the surveyor inquired about reasons why that product was not available, whether the product might be available to be purchased at a later date, and if so, when it would be available to be purchased. In this way, surveyors sought to discern whether certain products might be temporarily out-of-stock and available again at a later date, or whether they are not truly available. Surveyors sought to validate product availability by asking whether a product is available for immediate shipment, and if not when the product would be available to be shipped. Surveyors also asked if products other than those listed on Medicare.gov were available. The survey instrument can be found at Appendix C to this report.

Because a supplier's responses to the five different surveyors were not always uniformly consistent, we counted as a positive response to any question where at least three of the surveyors were given the same answer. For example, if three or more of the surveyors were told that a particular DTS product was available, that product was counted as available. By contrast, if two or fewer surveyors were told that a product was available, that product was counted as not available.

## **FINDINGS**

### **The mix of brands of diabetes testing supplies carried by NMO suppliers continues to decline**

Our studies have shown a continued shift in the market availability of diabetes testing supplies since the CBP was first implemented in 2009. During the initial phase of competitive bidding, suppliers offered Medicare beneficiaries DTS brands from 38 different manufacturers. This number fell to 34 with the implementation of NMO, and further fell to 20 with the implementation of the NMO recompetes. This nearly 50 percent reduction in brands of DTS offered by NMO suppliers underscores the complexities that Medicare beneficiaries experience when selecting a testing system. Reductions on this scale, especially when considered in light of data from the Inspector General showing that the brands most commonly used by beneficiaries before the CBP was implemented are no longer being carried by NMO suppliers, illustrate that beneficiaries have been made to switch DTS. Further underscoring this change, brands from 25 of the 38 manufacturers that were offered by suppliers under the initial CBP are not available under the NMO recompetes. This is of concern because, as suppliers limit choice, patients are at risk of being switched to DTS other than what was recommended by their healthcare team or preferred by the patient. The healthcare team including physicians and diabetes educators spend significant time and effort on educating beneficiaries on the appropriate use of the preferred DTS. Having to continuously re-educate beneficiaries because the beneficiary was switched, takes time away from the critical need to treat the beneficiary's diabetes.

## The mix of models of diabetes testing supplies in the market continues to decline

Additionally, the mix of models of DTS continues to decline. According to the MSD, under the NMO recompute suppliers offered 36 different models of DTS. This represents a dramatic reduction from the OIG's finding that suppliers submitted claims for at least 75 types of DTS from 31 different manufacturers for the three-month period ending December 2009.

Even more significant, the most common tests strips used by beneficiaries before implementation of the National Mail-Order Competitive Bidding Program are now no longer offered to beneficiaries by NMO suppliers. Our study showed that of the models of DTS currently available, most were not available prior to the implementation of the CBP. The table below shows the brands and models of DTS that were offered to Medicare beneficiaries in 2009 which are no longer offered by NMO suppliers. Many factors can contribute to a product no longer being commercialized; however, it should be concerning that since 2009 65 different models of DTS are no longer accessible by Medicare beneficiaries.

Table 1

DTS Models No Longer Available Under NMO			
Model	Manufacturer	Available November 2016 <sup>9</sup>	Available Oct-Dec 2009 <sup>10</sup>
Freestyle	Abbott	No	Yes
Freestyle Flash	Abbott	No	Yes
Medisense Optium	Abbott	No	Yes
Precision Xtra	Abbott	No	Yes
Liberty	Agamatrix	No	Yes
Wavesense Amp	Agamatrix	No	Yes
Wavesense Keynote	Agamatrix	No	Yes
Wavesense Pronto	Agamatrix	No	Yes
Companion	Apex	No	Yes
Advance Intuition	Arkray	No	Yes
Glucocard 01 Sensor	Arkray	No	Yes
Ascensia Auto Disc	Bayer	No	Yes
Ascensia Breeze 2	Bayer	No	Yes
Ascensia Contour	Bayer	No	Yes
Ascensia Contour TS	Bayer	No	Yes
Ascensia Elite	Bayer	No	Yes
One Touch Ultra	Bayer	No	Yes
Bionime	Bionime	No	Yes

<sup>9</sup> Source: MSD.

<sup>10</sup> Supra (4).



**DTS Models No Longer Available Under NMO**

<b>Model</b>	<b>Manufacturer</b>	<b>Available November 2016<sup>9</sup></b>	<b>Available Oct-Dec 2009<sup>10</sup></b>
<b>Glucocom</b>	Cardiocom	No	Yes
<b>Advocate Duo</b>	Diabetic Supply of Suncoast	No	Yes
<b>Prodigy Advance</b>	Diagnostic Devices	No	Yes
<b>Voice Prodigy</b>	Diagnostic Devices	No	Yes
<b>Easy Max</b>	ESP Bio Technologies	No	Yes
<b>Glucocom</b>	Glucocom	No	Yes
<b>Perfect 2</b>	GlucoPerfect	No	Yes
<b>Easy Check</b>	Home Aide Diagnostics	No	Yes
<b>Easy Plus</b>	Home Aide Diagnostics	No	Yes
<b>Liberty 2</b>	Home Diagnostics	No	Yes
<b>Prestige Smart System</b>	Home Diagnostics	No	Yes
<b>True Balance</b>	Home Diagnostics	No	Yes
<b>True Read</b>	Home Diagnostics	No	Yes
<b>True Track</b>	Home Diagnostics	No	Yes
<b>Eclipse</b>	Infopia	No	Yes
<b>Element</b>	Infopia	No	Yes
<b>Embrace</b>	Infopia	No	Yes
<b>Evolution</b>	Infopia	No	Yes
<b>True Track</b>	Invacare	No	Yes
<b>One Touch</b>	Lifescan	No	Yes
<b>One Touch Select</b>	Lifescan	No	Yes
<b>One Touch Sure Step</b>	Lifescan	No	Yes
<b>One Touch Ultra</b>	Lifescan	No	Yes
<b>One Touch Ultra 2</b>	Lifescan	No	Yes
<b>One Touch Ultra Smart in Duo</b>	Lifescan	No	Yes
<b>True Balance</b>	McKesson	No	Yes
<b>Precision Xtra</b>	Medisense	No	Yes
<b>Easy Max</b>	Oak Tree International Holdings	No	Yes
<b>Companion</b>	Omnis	No	Yes
<b>Embrace Companion</b>	Omnis	No	Yes
<b>Advocate</b>	Playtex	No	Yes
<b>Protégé</b>	Progressive	No	Yes
<b>SmartTest</b>	Progressive	No	Yes
<b>AccuCheck Active</b>	Roche	No	Yes
<b>AccuCheck Comfort Curve</b>	Roche	No	Yes
<b>AccuCheck Compact</b>	Roche	No	Yes
<b>AccuCheck Compact Plus</b>	Roche	No	Yes

<b>DTS Models No Longer Available Under NMO</b>			
<b>Model</b>	<b>Manufacturer</b>	<b>Available November 2016<sup>9</sup></b>	<b>Available Oct-Dec 2009<sup>10</sup></b>
<b>Clever Choice</b>	Simple Diagnostics	No	Yes
<b>Sure Classic</b>	Specialty Medical Supplies	No	Yes
<b>SureEdge</b>	Specialty Medical Supplies	No	Yes
<b>Acura</b>	US Diagnostics	No	Yes
<b>Control</b>	US Diagnostics	No	Yes
<b>Easy Gluco</b>	US Diagnostics	No	Yes
<b>Infinity</b>	US Diagnostics	No	Yes
<b>Maxima</b>	US Diagnostics	No	Yes
<b>Ultratrak Pro</b>	Vertex Diagnostics	No	Yes
<b>EZ Smart</b>	VIP International	No	Yes

### Many suppliers do not offer brands covering 50 percent of the market

The Medicare statute requires bidders for mail-order DTS to demonstrate that their bids cover at least 50 percent, by volume, of all types of DTS on the market (the “50 percent rule”).<sup>11</sup> Congress established this “50 percent rule” to ensure that Medicare beneficiaries continue to have access to a wide range of DTS as well as have access to the DTS that were available before implementation of the national CBP.

However, CMS has implemented this to be a requirement for the supplier’s bid only; according to CMS, the 50 percent rule is not a condition of on-going participation in the CBP. In other words, while a supplier is required to submit a bid based on the specific brands and models it may intend to make available, the supplier is not obligated to make available the range of products identified in its bid once it gets a contract from CMS. Congress could not have intended the 50 percent rule to allow prospective suppliers to submit bids that do not reflect the inventory the supplier will carry. Yet by failing to require suppliers to adhere to the 50 percent rule after a bid is accepted, this is precisely what CMS is allowing to happen.

The OIG has issued a series of five reports providing information about the market shares of diabetes test strips. Taken together, these reports show how those market shares changed with implementation of the Competitive Bidding Program.<sup>12</sup> In these reports, the OIG determined the relative market share of each testing system available. CMS used this information to determine if each supplier's bid met the 50 percent rule.<sup>13</sup>

<sup>11</sup> Social Security Act Section 1847(b)(10)(A).

<sup>12</sup> OEI-04-13-00680 Medicare Market Share of Mail-Order Diabetes Test Strips From July-September 2013 and OEI-04-13-00681 From April-June 2013.

<sup>13</sup> The Medicare Improvements for Patients and Providers Act of 2008, section 154(d)(3)(b) required the OIG to “conduct a study to determine the types of diabetic testing strip products by volume that could be used to make

The OIG findings can be found in Appendix D, E and F to this report.

When estimating the relative market share of supplier inventories for this study, AADE relied on the data contained in the most recent OIG report covering the period from April to June 2016. In this manner, the information in this report should reflect the most recently available data.

To determine the market share of each supplier's inventory we identified the brands of DTS each supplier carried according to the MSD, and determined the market share of each of those brands according to the most recent OIG report. We also identified the market share of brands that our surveyors found were actually available from each supplier. We considered a brand to be available if at least three surveyors were told that it was available from a supplier. We again used OIG market data to determine the market share of products reported to surveyors as being available. One caveat needs to be noted; the OIG study only reflects products made available by mail-order suppliers and does not reflect what patients are provided through the other channels, like retail pharmacies and storefront home medical equipment suppliers. The OIG study does not reflect the *overall* market share of products purchased by Medicare beneficiaries.

Figure 1 compares the market share of brands carried by each supplier according to the MSD with the market share of the brands actually carried by suppliers according to our surveys.

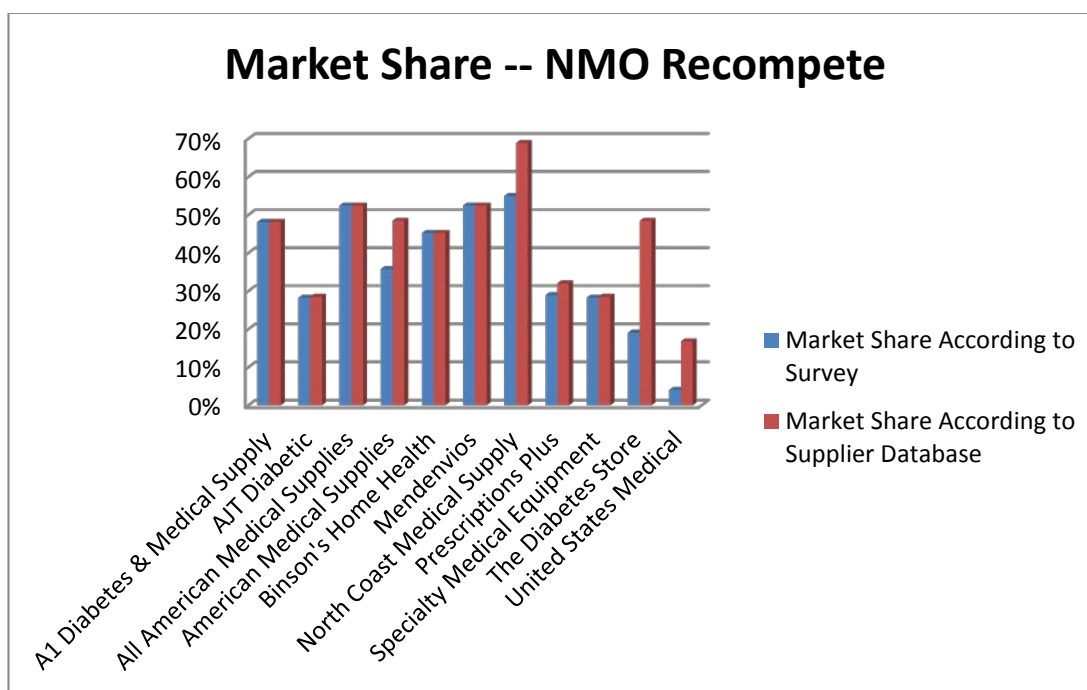


Figure 1: Market Share Comparison

determinations” as to whether a potential contract supplier’s bid covers products that account for at least 50% of the market share for such products.

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While this chart demonstrates that the information on Medicare's website has improved in its accuracy it is still troubling that most suppliers carry an inventory representing less than the 50 percent benchmark. It is even more troubling that one supplier only reported carrying a single brand of DTS that represents less than one percent market share.

For its 2016 report, the OIG selected a simple random sample of 1,210 claims submitted between April 1, 2016 and June 30, 2016.<sup>14</sup> While the OIG reported a 100 percent response rate to its survey, we note that the OIG's finding did not include claims for DTS manufactured by Diabetic Supplies of Suncoast, Diagnostic Devices, MedLine Industries and NIPRO. Both the MSD and our surveyors reported that NMO suppliers carry DTS by the manufacturers. When evaluating bids, CMS awards bidders an additional 10 percent market share if the bid included a diabetes test system other than one identified by the OIG. Even with this 10 percent "bonus," only five of the 11 suppliers would have inventory covering 50 percent of the market.

Although Congress clearly intended the 50 percent rule to ensure that beneficiaries would have access to the DTS offered before the NMO program, the reality is that beneficiaries do not have access to familiar and preferred DTS.

### **Information gathered from suppliers is inconsistent**

AADE also evaluated the consistency of the information provided by suppliers to surveyors.

Ideally, suppliers should give accurate and consistent answers about their available inventory 100 percent of the time.

In order to determine the consistency of the information available from NMO suppliers, the surveyors queried each supplier asking if particular brands of DTS were actually available for purchase from the supplier. We counted the number of times each surveyor was told by each supplier that a specific brand was available. We repeated this five times for each brand and each supplier over a 10 day period. We compared the information provided to the surveyors with the information available on the CMS website.

Table 2 illustrates that when a supplier is queried on different occasions about the brands available, the information received from the supplier is inconsistent and unreliable. In only two instances did a supplier give a consistent response to all five surveyors.

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<sup>14</sup> HHS Office of Inspector General; "Medicare Market Shares of Mail Order Diabetes Test Strips From April to June 2016. (OEI-04-16-00470); November 2016.

Table 2

	Number of Brands Available for Purchase					
	Per Supplier Database	Per Surveyor A	Per Surveyor B	Per Surveyor C	Per Surveyor D	Per Surveyor E
<b>A1 Diabetes &amp; Medical Supply</b>	6	6	5	6	2	3
<b>AJT Diabetic</b>	5	0*	3	3	3	3
<b>American Medical Supplies</b>	3	2	3	3	3	3
<b>All American Medical Supplies</b>	4	2	2	2	2	3
<b>Binson's Home Health</b>	4	4	4	4	4	4
<b>The Diabetes Store</b>	3	1	1	4	1	1
<b>North Coast Medical Supply</b>	11	11	10	0*	7	0*
<b>Prescriptions Plus</b>	5	5	0*	5	3	5
<b>Specialty Medical Equipment</b>	5	5	3	3	3	4
<b>United States Medical</b>	4	4	4	4	4	4
<b>Medenvios</b>	4	4	2	4	2	1

\*Surveyors were unable to contact suppliers and messages left by surveyors were not returned.

To account for normal fluctuations in inventory, if the supplier reported that the product was not available, the surveyor inquired about reasons why that product was not available, whether the product might be available to be purchased at a later date, and if so, when it would be available to be purchased. In this way, surveyors sought to discern whether certain products might be temporarily out-of-stock and available again at a later date, or whether they are truly not available. In some cases, surveyors were told that the supplier "never" carried a brand listed on Medicare.gov, while in other instances surveyors were told that the model was backordered or discontinued. In other instances, the supplier was unable to explain why a specific model was unavailable.

These data suggest that if a beneficiary were to call on different occasions or if multiple beneficiaries were to call the same supplier, they may receive conflicting information about product availability. Beneficiaries must be able to rely on product related information from the supplier when ordering DTS. Providing inconsistent information to callers should not be considered acceptable.

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## CONCLUSIONS

This study demonstrates that access to DTS continues to be limited, and that overall availability of different DTS has further deteriorated under the NMO recompetes. Limited availability of products from suppliers is compounded by the inconsistent information made available by suppliers. These two factors serve to make it difficult for beneficiaries to find preferred and familiar DTS.

Physicians, diabetes educators and other healthcare practitioners often prescribe specific DTS based on the needs of individual patients, along with their experiences with the reliability, performance and features of specific products. For example, some beneficiaries need audible readings or large displays because of poor vision. Providers may recommend DTS that are compatible with their office-based electronic medical record system. Different DTS are not interchangeable. When a beneficiary is forced to use a DTS that is unknown, difficult, confusing, or unreliable, adherence to testing may diminish, increasing the risk of complications, which can be costly for Medicare and its beneficiaries.

Effective and consistent self-monitoring of blood glucose levels is essential to diabetes control. Increased risk of devastating and costly complications, such as blindness, kidney damage, cardiovascular disease, and lower-limb amputations are associated with inadequate blood glucose control. If beneficiary access to the most appropriate or familiar DTS is disrupted, patient compliance with monitoring regimens may decrease, and adverse health complications may increase.

Unfortunately, the lack of product availability and the lack of consistent information about product availability are leading to the unintended consequence of beneficiaries switching to different brands of DTS. AADE believes that Medicare beneficiaries should not feel pressured or have their choice of DTS compromised by suppliers' switching them from the DTS with which they are familiar. However, the restrictions placed on the availability of supplies due to limited suppliers and the inaccurate information is doing just that.

## RECOMMENDATIONS

This study demonstrates the need for Congress and CMS to immediately address a number of flaws in the NMO program.

- 1) CMS should strengthen beneficiary protection requirements for future rounds of competitive bidding by requiring as a condition of continued participation in the competitive bidding program and not just as a condition of bid acceptance, that all suppliers continue to provide the same mix of brands and models as that which their bid acceptance was based upon.

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2) CMS should regularly audit competitive bidding suppliers to ensure that they continue to meet all DME supplier standards for accreditation and quality. Audits must also include an evaluation of the supplier's continued adherence to program rules. CMS should also develop a corrective action plan program for suppliers who fail to adhere to statutory and regulatory requirements. Such plan should include removal from the program for suppliers with egregious and/or continued violation of programmatic rules.

## **CONTACTS**

For more information about AADE or this study, please contact Kurt Anderson, Director of Federal and State Advocacy at [kanderson@aadenet.org](mailto:kanderson@aadenet.org).

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## Appendix A

<b>National Mail-Order Reconnect Suppliers</b>
1. A1 Diabetes & Medical Supply
2. AJT Diabetic Incorporated/Countrywide Medical
3. All American Medical Supplies, LLC **
4. American Medical Supplies, Inc. **
5. Binson's Hospital Supplies/Binson's Home Health Care Centers**
6. The Diabetes Store Inc.
7. Medenvios HealthCare, Inc.
8. North Coast Medical Supply/Advanced Diabetes Supply
9. Prescriptions Plus, Inc.
10. Specialty Medical Equipment Inc.
11. United States Medical Supply, Inc.**

Suppliers marked with "\*\*\*" served as contract suppliers under National Mail-Order Round 1.



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## Appendix B

<b>National Mail-Order Round 1 Suppliers</b>
1. All American Medical Supplies, Inc.**
2. All-States Medical Supply, Inc.
3. American Medical Supplies, Inc.**
4. Am-Med Diabetic Supplies, Inc.
5. Arriva Medical, LLC
6. Binson's Hospital Supplies, Inc.,**
7. Care Services, Inc.
8. DEGC Enterprises (U.S.), Inc.
9. Diabetes Care Club
10. Diagnostics Unlimited
11. Enteral Products, LLC
12. Home Care Delivered, Inc.
13. Home Delivery Incontinent Supplies Co., Inc.
14. Jade Diabetic Group LLC/Canyon Health Care LLC/101 Diabetic Supply
15. Kohll's Pharmacy & Homecare, Inc.
16. Lake Diabetes & Medical Supply, Inc./A1 Diabetes & Medical Supply
17. Lincare Pharmacy Services, Inc./Reliant Pharmacy Service/Diabetes Experts of America
18. Longcap DNS, LLC/Envoy Health
19. Med-Care Diabetic and Medical Supplies
20. United States Medical Supply, Inc.**

Suppliers marked with "\*\*\*" have been awarded contracts under the National Mail-Order Re compete



## Appendix D

### Market Share Estimates and Their 95-Percent Confidence Intervals for 75 Types of Mail-Order Diabetic Testing Strips (October – December 2009)

Manufacturer	Model	Percentage of Market Share	95-Percent Confidence Interval for Market Share
Abbott	Freestyle	2.09	1.30–3.34
Abbott	Freestyle Flash	0.11	0.01–0.75
Abbott	Freestyle Lite	7.32	5.77–9.21
Abbott	Medisense Optium	4.46	3.29–6.01
Abbott	Precision Xtra	0.04	0.01–0.30
Agamatrix	Liberty	3.09	2.14–4.41
Agamatrix	Wavesense Amp	0.08	0.01–0.60
Agamatrix	Wavesense Keynote	0.13	0.02–0.89
Agamatrix	Wavesense Presto	2.41	1.60–3.62
Apex	Companion	0.38	0.14–1.03
Arkray	Advance Intuition	0.13	0.02–0.89
Arkray	Glucocard 01 Sensor	0.08	0.02–0.34
Bayer	Ascensia Auto Disc	0.51	0.23–1.12
Bayer	Ascensia Breeze 2	5.01	3.75–6.65
Bayer	Ascensia Contour	11.1	9.24–13.25
Bayer	Ascensia Contour TS	3.28	2.36–4.52
Bayer	Ascensia Elite	0.17	0.05–0.56
Bayer	One Touch Ultra	0.04	0.01–0.30
Bionime	Bionime	0.47	0.20–1.09
Cardiocom	GlucoCom	0.13	0.02–0.89
Diabetic Supply of Suncoast	Advocate	0.63	0.30–1.34
Diabetic Supply of Suncoast	Advocate Duo	0.21	0.07–0.68
Diabetic Supply of Suncoast	Advocate Redi-Code	1.78	1.13–2.78
Diagnostic Devices	Prodigy Advance	0.08	0.01–0.60
Diagnostic Devices	Prodigy Autocode	2.33	1.55–3.46
Diagnostics Devices	Voice Prodigy	0.38	0.12–1.22
ESP Bio Technologies	Easy Max	0.04	0.01–0.30
GlucoCom	GlucoCom	0.08	0.02–0.34
GlucoPerfect	Perfect 2	0.02	0.00–0.15
Home Aide Diagnostics	Easy Check	1.35	0.76–2.40
Home Aide Diagnostics	Easy Plus	0.36	0.11–1.16
Home Diagnostics	Liberty 2	1.9	1.17–3.07
Home Diagnostics	Prestige Smart System	0.21	0.05–0.86

**Market Share Estimates and Their 95-Percent Confidence Intervals for 75 Types of Mail-Order Diabetic Testing Strips (October – December 2009)**

<b>Home Diagnostics</b>	True Balance	3	2.06–4.35
<b>Home Diagnostics</b>	True Read	1.61	1.00–2.58
<b>Home Diagnostics</b>	TrueTrack	1.86	1.17–2.93
<b>Infopia</b>	Eclipse	0.47	0.20–1.09
<b>Infopia</b>	Element	0.97	0.51–1.86
<b>Infopia</b>	Embrace	0.08	0.01–0.60
<b>Infopia</b>	Evolution	0.38	0.13–1.08
<b>Invacare</b>	TrueTrack	0.08	0.01–0.60
<b>Lifescan</b>	One Touch	0.38	0.14–1.03
<b>Lifescan</b>	One Touch Select	0.76	0.40–1.46
<b>Lifescan</b>	One Touch Sure Step	0.08	0.01–0.60
<b>Lifescan</b>	One Touch Ultra	14.88	12.61–17.44
<b>Lifescan</b>	One Touch Ultra 2	0.51	0.21–1.20
<b>Lifescan</b>	One Touch Ultra Smart In Duo	0.04	0.01–0.30
<b>McKesson</b>	True Balance	0.04	0.01–0.30
<b>Medisense</b>	Precision Xtra	0.04	0.01–0.30
<b>Medline Industries</b>	Evencare	0.08	0.01–0.60
<b>Nova Biomedical</b>	Nova Max	1.46	0.86–2.47
<b>Oak Tree International Holding</b>	Easy Max	0.63	0.30–1.33
<b>Omnis Health</b>	Companion	1.82	1.14–2.88
<b>Omnis Health</b>	Embrace	4.02	2.93–5.47
<b>Omnis Health</b>	Embrace Companion	0.08	0.02–0.34
<b>Playtex</b>	Advocate	0.04	0.01–0.30
<b>Progressive</b>	Protégé	0.13	0.03–0.54
<b>Progressive</b>	SmartTest	0.08	0.01–0.60
<b>Roche</b>	AccuCheck Active	0.93	0.49–1.76
<b>Roche</b>	AccuCheck Aviva	4.76	3.50–6.42
<b>Roche</b>	AccuCheck Comfort Curve	0.87	0.37–1.99
<b>Roche</b>	AccuCheck Compact	4.12	3.00–5.62
<b>Roche</b>	AccuCheck Compact Plus	0.44	0.19–1.04
<b>Simple Diagnostics</b>	Clever Check	1.08	0.61–1.89
<b>Simple Diagnostics</b>	Clever Check Voice	0.72	0.34–1.52
<b>Simple Diagnostics</b>	Clever Choice	0.17	0.04–0.79
<b>Specialty Medical Supplies</b>	Sure Classic	0.25	0.06–1.01
<b>Specialty Medical Supplies</b>	SureEdge	0.25	0.09–0.71

**Market Share Estimates and Their 95-Percent Confidence Intervals for 75 Types of Mail-Order Diabetic Testing Strips (October – December 2009)**

<b>US Diagnostics</b>	Acura	0.3	0.07–1.19
<b>US Diagnostics</b>	Control	0.21	0.07–0.59
<b>US Diagnostics</b>	Easy Gluco	0.8	0.38–1.67
<b>US Diagnostics</b>	Infinity	0.3	0.10–0.87
<b>US Diagnostics</b>	Maxima	0.8	0.41–1.57
<b>Vertex Diagnostics</b>	Ultratrak Pro	0.13	0.02–0.89
<b>VIP International</b>	EZ-Smart	0.04	0.01–0.30
<b>Total</b>		<b>100.00*</b>	

Source: Office of Inspector General analysis of supplier documentation and Medicare HCPCS code A4253 KL claims data for the 3-month period ending December 2009. (OEI-04-10-00130)

\* Column does not sum to total because of rounding.

## Appendix E

### Market Share Estimates and Their 95-Percent Confidence Intervals for 41 Types of Mail-Order Diabetes Test Strips for the 3-Month Period of October to December 2013

Manufacturer	Model	Percentage of Market Share	95-Percent Confidence Interval for Market Share
Roche	ACCU-CHEK Aviva	0.04%	0.01–0.17%
Simple Diagnostics	Clever Choice Pro	0.04%	0.01–0.17%
BIONIME USA Corporation	GM100	0.04%	0.01–0.17%
ACON Laboratories, Inc.	On-Call Vivid	0.04%	0.01–0.17%
Nipro Diagnostics, Inc.	TRUEtrack	0.04%	0.01–0.17%
ForaCare, Inc.	V10/D20	0.04%	0.01–0.17%
Agamatrix, Inc.	WaveSense Presto	0.04%	0.01–0.17%
Bayer HealthCare LLC	BREEZE 2	0.09%	0.03–0.23%
Home Aide Diagnostics	Easy Plus II	0.09%	0.03–0.23%
Home Aide Diagnostics	Easy Step	0.09%	0.03–0.23%
Infopia USA	Element	0.09%	0.03–0.23%
Infopia USA	Element Compact	0.09%	0.03–0.23%
Simple Diagnostics	Clever Choice Voice Plus	0.13%	0.06–0.28%
Home Aide Diagnostics	Easy Talk	0.13%	0.06–0.28%
Home Aide Diagnostics	Easy Trak	0.13%	0.06–0.28%
Abbott Diabetes Care	FreeStyle Lite	0.13%	0.06–0.28%
AgaMatrix, Inc.	Liberty Autocode	0.13%	0.06–0.28%
i-Sens	Care Sens	0.17%	0.09–0.34%
i-Sens	Care Sens N	0.17%	0.09–0.34%
ARKRAY	GLUCOCARD Expression	0.17%	0.09–0.34%
US Diagnostics	INFINITY	0.26%	0.15–0.45%
LifeScan, Inc.	OneTouch Verio	0.28%	0.16–0.48%
ARKRAY	GLUCOCARD Vital	0.30%	0.18–0.50%
Roche	ACCU-CHEK Nano Smartview*	0.38%	0.24–0.61%
Gluco Perfect	Perfect 3	0.43%	0.27–0.66%
BioSense Medical Devices	Solo V2	0.47%	0.31–0.71%
BIONIME USA Corporation	GS300	0.77%	0.55–1.06%
Nova Biomedical	NovaMax	0.77%	0.55–1.06%
Roche	ACCU-CHEK Compact Plus	0.83%	0.61–1.13%
Diabetic Supply of Suncoast, Inc.	Advocate	0.98%	0.73–1.31%
Roche	ACCU-CHEK Aviva Plus	1.21%	0.94–1.57%

<b>Market Share Estimates and Their 95-Percent Confidence Intervals for 41 Types of Mail-Order Diabetes Test Strips for the 3-Month Period of October to December 2013</b>			
<b>Simple Diagnostics</b>	Clever Choice Voice	1.28%	0.99–1.64%
<b>Bayer HealthCare LLC</b>	CONTOUR	1.55%	1.24–1.95%
<b>BioSense Medical Devices</b>	SolusV2	2.13%	1.75–2.58%
<b>Diabetic Supply of Suncoast, Inc.</b>	Advocate Redi-Code +	2.34%	1.95–2.82%
<b>Omnis Health</b>	Embrace	11.37%	10.49–12.31%
<b>LifeScan, Inc.</b>	OneTouch Ultra Blue	14.31%	13.34–15.34%
<b>Nipro Diagnostics, Inc.</b>	TRUEtest	16.91%	15.86–18.01%
<b>Prodigy Diabetes Care</b>	Prodigy AutoCode	26.92%	25.65–28.19%
<b>LifeScan, Inc.</b>	OneTouch Ultra	4.02%	3.50–4.63%
<b>Philosys, Inc.</b>	Gmate	10.63%	9.78–11.54%
<b>Total</b>		100.00% **	

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of October to December 2013. (OEI-04-13-00682)

\*This diabetes test strip may also be listed as the ACCU-CHEK Nano SmartView.

\*\*Because of rounding, the percentages in this column do not sum to the total.

## Appendix F

Market Share Estimates and their 95 Percent Confidence Intervals for 30 Types of Mail-Order Diabetes Test Strips for the 3-month Period April - June 2016			
Manufacturer	Model	Market Share	95-Percent Confidence Interval
ACON Laboratories	On Call Express	0.04%	0.01–0.28%
ACON Laboratories	On Call Plus	0.28%	0.08–0.99%
ARKRAY	Glucocard Vital	0.04%	0.01–0.28%
Bionime Corporation	Rightest GS 300	0.63%	0.30–1.31%
BioSense Medical Devices	SolusV2	1.16%	0.55–2.42%
BroadMaster Bio-Tech Corp.	ADVOCATE Redi-Code+	2.46%	1.62–3.73%
Home Aide Diagnostics	Easy Talk	0.51%	0.22–1.18%
Infopia USA LLC	Element Compact	0.63%	0.30–1.34%
Infopia USA LLC	Element Plus	0.12%	0.02–0.84%
i-Sens, Inc.	CareSens N	0.16%	0.04–0.63%
i-Sens, Inc.	CareSens Strips	7.43%	5.90–9.31%
LifeScan, Inc.	OneTouch Ultra	22.82%	20.07–25.83%
LifeScan, Inc.	OneTouch Verio	0.24%	0.05–1.01%
Nova Biomedical	Nova Max	0.73%	0.30–1.78%
Oak Tree International Holdings, Inc.	EasyMax	0.04%	0.01–0.28%
Omnis Health	Embrace	11.49%	9.65–13.63%
Panasonic Health Holdings Co., Ltd.	Breeze 2	0.28%	0.08–0.93%
Panasonic Healthcare Holdings Co., Ltd.	CONTOUR	2.60%	1.75–3.84%
Panasonic Healthcare Holdings Co., Ltd.	CONTOUR NEXT	2.64%	1.58–4.38%
Philosys	Gmate	3.09%	2.25–4.25%
Prodigy Diabetes Care	Prodigy	28.22%	25.37–31.07%
Roche	ACCU-CHEK Aviva Plus	0.55%	0.24–1.27%
Roche	ACCU-CHEK Compact Plus	0.37%	0.15–0.92%
Roche	ACCU-CHEK SmartView*	0.30%	0.11–0.82%
Simple Diagnostics	Clever Choice	0.04%	0.01–0.28%
Simple Diagnostics	Clever Choice Voice	0.16%	0.05–0.52%
Trividia Health, Inc.	TRUEmetrix	1.69%	1.03–2.78%
Trividia Health, Inc.	TRUEtest	10.98%	9.11–13.17%
Trividia Health, Inc.	TRUEtrack	0.04%	0.01–0.28%
Unistrip Technologies, LLC	Unistrip1	0.26%	0.06–1.06%
Total		<b>100.00%**</b>	

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of April to June 2016. (OEI-04-16-00470)

\*This diabetes test strip may also be listed as the ACCU-CHEK Nano SmartView.

\*\*The percentages in this column do not sum to the total because of rounding.



## Appendix G

<b>Manufacturer and Models of Mail-Order Diabetes Test Strips Available through National Mail-Order Reconnect Suppliers</b>	
<b>Manufacturer</b>	<b>Model</b>
<b>Abbott</b>	Freestyle Lite
<b>Acon Labs</b>	On Call Express
<b>Acon Labs</b>	On Call Plus
<b>Arkray</b>	Glucocard Expression
<b>Arkray</b>	Glucocard Vital
<b>Bayer</b>	Contour
<b>Bayer</b>	Contour Next
<b>BioSense Medical Devices</b>	Solo V2
<b>BioSense Medical Devices</b>	Solus V2
<b>Diabetic Supply of Suncoast</b>	Advocate
<b>Diabetic Supply of Suncoast</b>	Advocate Redi-Code
<b>Diabetic Supply of Suncoast</b>	Advocate Redi-Code Plus
<b>Diagnostic Devices</b>	Prodigy Autocode
<b>Home Aide Diagnostics</b>	Easy Plus II
<b>Home Aide Diagnostics</b>	Easy Step
<b>Home Aide Diagnostics</b>	Easy Talk
<b>Home Aide Diagnostics</b>	Easy Trak
<b>I-Sens</b>	Caresens
<b>I-Sens</b>	Caresens N
<b>MedLine Industries</b>	Evencare
<b>NIPRO (Previously Home Diagnostics)</b>	TRUEbalance
<b>NIPRO (Previously Home Diagnostics)</b>	TRUEresult
<b>NIPRO (Previously Home Diagnostics)</b>	TRUEtest
<b>NIPRO (Previously Home Diagnostics)</b>	TRUEmetrix
<b>NIPRO (Previously Home Diagnostics)</b>	TRUEtrack
<b>Nova Biomedical/Sanvita</b>	NovaMax
<b>Oak Tree International Holdings</b>	Easymax V
<b>Omnis</b>	Embrace
<b>Philosys</b>	Gmate
<b>Prodigy</b>	Prodigy Autocode
<b>Roche</b>	Accu-chek Aviva
<b>Simple Diagnostics</b>	Clever Choice Voice
<b>Simple Diagnostics</b>	Clever Choice Voice Plus
<b>Simple Diagnostics</b>	Clever Chek
<b>Trividia</b>	True Metrix
<b>Unistrip Technologies LLC</b>	Unistrip 1