

# Article - Response to Comments: MoIDX: AlloSure® Donor-Derived Cell-Free DNA Test (A55760)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01111 - MAC A	J - E	California - Entire State
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01112 - MAC B	J - E	California - Northern
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01182 - MAC B	J - E	California - Southern
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01311 - MAC A	J - E	Nevada
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01312 - MAC B	J - E	Nevada
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

## Article Information

### General Information

Article ID

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**Article Title**

Response to Comments: MolDX: AlloSure® Donor-Derived Cell-Free DNA Test

**Article Type**

Response to Comments

**Original Effective Date**

12/11/2017

**Retirement Date**

N/A

**Article Guidance****Article Text**

The comment period for the MolDX: AlloSure® Donor-Derived Cell-Free DNA Test (LCD) began on 06/01/2017 and ended on 08/14/2017. Comments were received from the provider community. The notice period begins on 10/25/2017 and ends 12/10/2017. The LCD becomes final on 12/11/2017.

**Response to Comments**

NUMBER	COMMENT	RESPONSE
1	The AlloSure testing for graft rejection in renal cell transplant may be utilized for determining need for multiple immunosuppressive medications with impending graft rejection. This test may be utilized again once patient is back to monotherapy with calcineurin drug if there is rise in creatinine. One tries if possible to avoid renal biopsies. I can	Allograft rejection can occur at any time post-transplant, although it is generally more of a concern during the first year. Guidelines that recommend frequency of testing with other non-invasive tests takes this occurrence of rejection into consideration and recommend greater frequency in the first year and decreased frequency in the years beyond the first year, but informed by individualized clinical suspicion of rejection. In both the Bromberg publication (JALM, 2017) and in Bloom, et al (JASN, 2017), the DART data indicate that many clinically indicated biopsies can be avoided if AlloSure is used to inform on the probability of rejection

NUMBER	COMMENT	RESPONSE
	see why this testing would be used more than once.	at the time of clinical suspicion. Since a biopsy is not frequently performed for surveillance due to its invasive nature, the use of AlloSure may be performed at a frequency established for other non-invasive tests such as viral testing and donor-specific antibody testing (4-6x during the first year; 2-4x in subsequent years). AlloSure testing may also be performed to assess the probability of rejection prior to deciding on an unscheduled (non-protocol) biopsy.

## Associated Documents

### Related Local Coverage Documents

#### LCDs

[DL37303 - \(MCD Archive Site\)](#)

[L37303 - \(MCD Archive Site\)](#)

### Related National Coverage Documents

N/A

#### Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
10/11/2017	12/11/2017 - N/A	Currently in Effect (This Version)

## Keywords

- Allosure
- MoIDX