

検査内容変更のお知らせ

謹啓 時下ますますご清栄のこととお慶び申し上げます。
平素は格別のご高配を賜り厚くお礼申し上げます。
下記検査項目におきまして、測定委託先の報告書が一部変更されましたのでご案内いたします。
健康と医療の未来に貢献すべく、より良い検査サービスのご提供に努めてまいります。

謹白

記

■ 変更日

2024年11月5日（火）9:00以降のMail Gateへのご報告分より

■ 対象項目

項目コード (旧項目コード)	検査項目
O2690 3 (2690 5)	BRCA1/2 遺伝子検査（乳癌）
OR221 8 (R221 7)	BRCA1/2 遺伝子検査（卵巣癌）
OR638 6 (R638 8)	BRCA1/2 遺伝子検査（HBOC）
OU052 3 (U052 0)	BRCA1/2 遺伝子検査（膵癌）
OR629 6 (R629 0)	BRCA1/2 遺伝子検査（前立腺癌）
OR615 1 (R615 5)	BRCA1/2 遺伝子シングルサイト検査

■ 変更内容

報告書1枚目の判定コメントの注釈が変更または削除されます。
変更点を赤枠で示しましたので、詳細は裏面をご確認ください。



新	現																		
<p>CONFIDENTIAL</p> <p>BRCAAnalysis診断システム® BRCA1 and BRCA2 Analysis Result</p> <p>RECEIVING HEALTHCARE PROVIDER: Test HCF, MD, Test Institution 0000, 123 Main Street, Okinawa 000-0000, Japan</p> <p>SPECIMEN: Specimen Type: Blood, Draw Date: Oct 02, 2024, Accession Date: Oct 02, 2024, Report Date: Oct 04, 2024</p> <p>PATIENT: Legal Name: 00-0000, XXXXX, Date of Birth: Mar 16, 1980, Patient ID: 000-XXXX-0000, Sex at Birth: F, Accession #: 07367080-BLD, Requestor #: 47791219</p> <p>GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED</p> <table border="1"> <thead> <tr> <th>GENE</th> <th>MUTATION</th> <th>INTERPRETATION</th> </tr> </thead> <tbody> <tr> <td>BRCA1</td> <td>c.48_59del (p.Gln29Valfs*17)</td> <td>DELETERIOUS</td> </tr> </tbody> </table> <p>TREATMENT IMPLICATIONS: Patients with breast, ovarian, pancreatic, or prostate cancer who have deleterious or suspected deleterious germline BRCA1 or BRCA2 mutations may be eligible for treatment with Lynparza® (olaparib).</p> <p>ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED</p> <p>Genes Analyzed: Unless otherwise noted sequencing and large rearrangement analyses were performed on the following genes: BRCA1, BRCA2</p> <p>Intended Use: This device is used as an aid for detecting germline BRCA1 or BRCA2 gene mutations in genomic DNA extracted from whole blood and for determining the eligibility of patients with breast, ovarian, pancreatic, or prostate cancer for olaparib treatment or patients with breast cancer for talazoparib treatment.</p>	GENE	MUTATION	INTERPRETATION	BRCA1	c.48_59del (p.Gln29Valfs*17)	DELETERIOUS	<p>CONFIDENTIAL</p> <p>BRCAAnalysis診断システム® BRCA1 and BRCA2 Analysis Result</p> <p>RECEIVING HEALTHCARE PROVIDER: Test HCF, MD, Test Institution 0000, 123 Main Street, Okinawa 000-0000, Japan</p> <p>SPECIMEN: Specimen Type: Blood, Draw Date: Feb 20, 2024, Accession Date: Feb 20, 2024, Report Date: Feb 26, 2024</p> <p>PATIENT: Legal Name: 00-0000, XXXXX, Date of Birth: Feb 20, 1980, Patient ID: 000-XXXX-0000, Sex at Birth: F, Accession #: 07366415-BLD, Requestor #: 47791220</p> <p>GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED</p> <p>Note: "CLINICALLY SIGNIFICANT," as defined in this report, is a genetic change that is associated with the potential to alter medical intervention.</p> <table border="1"> <thead> <tr> <th>GENE</th> <th>MUTATION</th> <th>INTERPRETATION</th> </tr> </thead> <tbody> <tr> <td>BRCA1</td> <td>c.2223-2del? (Heterozygous)</td> <td>SUSPECTED DELETERIOUS</td> </tr> </tbody> </table> <p>TREATMENT IMPLICATIONS: Patients with breast, ovarian, pancreatic, or prostate cancer who have deleterious or suspected deleterious germline BRCA1 or BRCA2 mutations may be eligible for treatment with Lynparza® (olaparib).</p> <p>ADDITIONAL FINDINGS: VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED</p> <table border="1"> <thead> <tr> <th>GENE</th> <th>VARIANT(S) OF UNCERTAIN SIGNIFICANCE</th> <th>INTERPRETATION</th> </tr> </thead> <tbody> <tr> <td>BRCA1</td> <td>c.2142G>C (p.Gln704Ser); (fs) G1048A (32k254C)</td> <td>UNCERTAIN CLINICAL SIGNIFICANCE</td> </tr> </tbody> </table> <p>ADDITIONAL INFORMATION: Genes Analyzed: Unless otherwise noted sequencing and large rearrangement analyses were performed on the following genes: BRCA1, BRCA2</p> <p>Intended Use: This device is used as an aid for detecting germline BRCA1 or BRCA2 gene mutations in genomic DNA extracted from whole blood and for determining the eligibility of patients with breast, ovarian, pancreatic, or prostate cancer for olaparib treatment or patients with breast cancer for talazoparib treatment.</p>	GENE	MUTATION	INTERPRETATION	BRCA1	c.2223-2del? (Heterozygous)	SUSPECTED DELETERIOUS	GENE	VARIANT(S) OF UNCERTAIN SIGNIFICANCE	INTERPRETATION	BRCA1	c.2142G>C (p.Gln704Ser); (fs) G1048A (32k254C)	UNCERTAIN CLINICAL SIGNIFICANCE
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陽性報告書の変更部分抜粋：判定コメントの注釈が削除されます。

新	<p>GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED</p>	
	<p>遺伝子検査の結果：陽性 - 臨床的意義のある変異が同定されました</p>	
現	<p>GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED</p> <p>Note: "CLINICALLY SIGNIFICANT," as defined in this report, is a genetic change that is associated with the potential to alter medical intervention.</p>	
	<p>遺伝子検査の結果：陽性 - 臨床的意義のある変異が同定されました</p> <p>注記：本報告書で定義する「臨床的意義がある」とは、医学的介入を変更する可能性を伴う遺伝子変化です。</p>	

陰性・VUS 報告書の変更部分抜粋：判定コメントの注釈が変更になります。

新	<p>GENETIC RESULT: NEGATIVE - NO CLINICALLY SIGNIFICANT MUTATION IDENTIFIED</p> <p>At this time, any genetic changes identified in this report are not known to warrant modification of the patient's medical management beyond what is indicated by the patient's personal and family history.</p>	
	<p>遺伝子検査の結果：陰性 - 臨床的意義のある変異は同定されませんでした</p> <p>現時点では、この報告書で認められた遺伝的変化が、患者の既往歴や家族歴に基づく医学的管理を変更する必要性は認められていません</p>	
現	<p>GENETIC RESULT: NEGATIVE - NO CLINICALLY SIGNIFICANT MUTATION IDENTIFIED</p> <p>Note: "CLINICALLY SIGNIFICANT," as defined in this report, is a genetic change that is associated with the potential to alter medical intervention.</p>	
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※プログラム医療機器として承認を受けているのは英語報告書です。日本語報告書は参考で、結果によっては付かないこともあります。