GIMA

PROFESSIONAL MEDICAL PRODUCTS

TEST DEL DALTONISMO - TESTS FOR COLOUR DEFICIENCY
TESTS POUR DALTONISME - TESTS FÜR FARBSCHWÄCHE
PRUEBAS DE DEFICIENCIA DE COLOR
TESTES DE DEFICIÊNCIA DE CORES - ΤΕΣΤ ΑΧΡΩΜΑΤΟΨΙΑΣ
TESTY BADAJĄCE WIDZENIE KOLORÓW
TESTE PENTRU ANOMALII DE PERCEPȚIE A CULORII
TESTY FARBOSLEPOSTI - SPALVU SKYRIMO TESTAI
اختبار فعالية اللون

È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.

Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

Należy poinformować producenta i kompetentne władze danego Kraju członkowskiego o każdym poważnym wypadku związanym z wyrobem medycznym naszej produkcji.

Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul.

Všetky vážne nehody súvisiace s nami dodanou zdravotníckou pomôckou je potrebné nahlásiť výrobcovi a kompetentnému úradu v členskom štáte, v ktorom sa pomôcka používa.

Apie visus rimtus nelaimingus atsitikimus, susijusius su mūsų tiekiama medicinos priemone, privaloma pranešti gamintojui ir tos valstybės, kurioje yra jūsų registruota buveinė, kompetentingai institucijai.

يجب الإبلاغ فورا عن أي حادث خطير وقع فيما يتعلق بالجهاز الطبي الذي زودنا به إلى الجهة الصانعة والسلطة المختصة في الدولة العضو التي يقع فيها

REF **31286 - 31287**

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Introduction

The plates for color blindness testing are designed to provide a test which gives a quick and accurate assessment of color vision deficiency of congenital origin.
Most cases of congenital color vision deficiency are characterized by a red-green deficiency.
There is also a very rare group of persons who suffer from total color blindness and show a complete failure to discriminate any color variations, usually with an associated impairment of central vision with photophobia and nystagmus.
Furthermore, a failure in the appreciation of blue and yellow may be termed tyritanomalia if partial, and tritanopia if complete, but, even if such cases do exist, they are extremely rare. The plates are not designed for the diagnosis of such cases.
The pedriatric series of plates 31286 is provided to detect colour blindness in person from 4 to 6 years of age or in persons who can not read.

Only a trained eye care professional can properly diagnose vision disorders, home use of the charts is not a replacement for professional vision testing.

How to use the test

The plates are designed to be appreciated correctly in a room which is lit adequately by daylight. The introduction of direct sunlight or the use of electric light may produce some discrepancy in the results because of an alteration in the appearance of shades of color. When it is convenient only to use electric light, it should be adjusted as far as possible to resemble the effect of natural daylight.
The plates should be held at a distance of approx 70 cm. from the subject and tilted so that the plane of the paper is at right angles to the line of vision.
The numerals or symbols which are seen on plates are stated, and each answer should be given without more than three seconds delay. It is not necessary in all cases to use the whole series of plates.

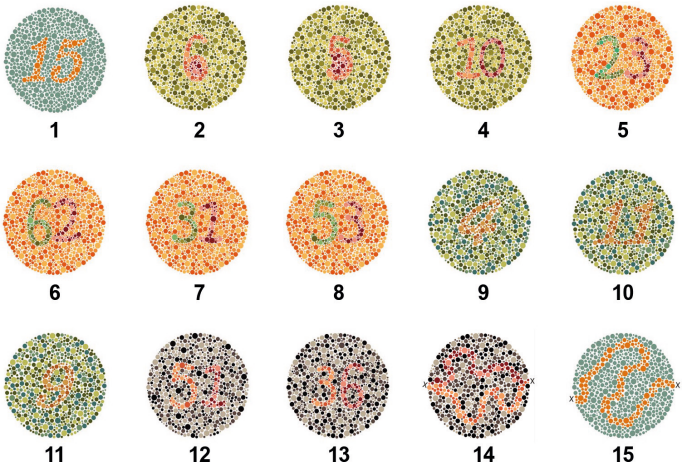
Care of plates

The avoid fading of the colors; care must be taken to keep the plates store in case except during use and not to expose the plates to strong light. Tracing curves must be soft in order to prevent scratching.

Explanation of the plates for adults 31287

No.1. Any subject, whether with normal or defective color vision will read correctly the figures “15”. This plate is used mainly for preliminary explanation of the test process to the subjects.
No.2. Normal subjects will read “6” and those with red-green deficiencies can see only dot inside of “6”.
No.3. Normal subjects will read “5” and those with red-green deficiencies can see only dot inside of “5”.
No.4. Normal subjects will read “10” and those with red-green deficiencies can see only No. “0”.
No.5. Normal subjects will read “23” and those with red-green deficiencies can see only No. “3”.
No.6. Normal subjects will read “62” and those with red-green deficiencies can see only No. “2”.
No.7. Normal subjects will read “31” and those with red-green deficiencies can see only No. “1”.
No.8. Normal subjects will read “53” and those with red-green deficiencies can see only No. “3”.
No.9. Correctly decipherable by normal subjects, but illegible or hard to read for those with red-green deficiencies.
No.10. Correctly decipherable by normal subjects, but illegible or hard to read for those with red-green deficiencies.
No.11. Correctly decipherable by normal subjects, but illegible or hard to read for those with red-green deficiencies.
No.12. Normal subjects and those with mild red-green deficiencies see the figures “51” but protanopia and strong protanomalia will read “1” only, and deuteranopia and strong deuteranomalia “5” only.
No.13. Normal subjects and those with mild red-green deficiencies see the figures “36” but protanopia and strong protanomalia will read “6” only, and deuteranopia and strong deuteranomalia “3” only.
No.14. In tracing the winding lines between the two X’s, the normal trace along the purple and

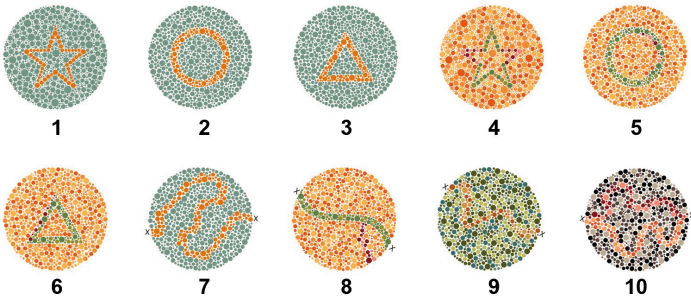
red lines. In protanopia and strong protanomalia only the purple line is traced, and in case of mild protanomalia both lines are traced but the purple line is easier to follow. In deuteranopia and strong deuteranomalia only the red line is traced and in case of mild deuteranmalia both lines are traced but the red line is easier to follow.
No.15. In tracing the winding line between the two X's, both the normal and those with color vision deficiencies are able to trace the line.



Analysis of the results
As assessment of the readings of plates 1 to 11 determines the normality or defectiveness of color vision.
If 10 or more plates are read normally, the color vision is regarded as normal. If only 7 or less than 7 plates are read normal, the color vision is regarded as deficient. It is rare to find a person whose recording of normal answers is 8 or 9 plates. An assessment of such a case requires the use of other color vision tests, including the anomaloscope.

Explanation of the pediatric plates 31286
The First examination is performed with a STAR, CIRCLE AND TRIANGLE. Before the examination, it is necessary to make sure that the examinee understands what he is being asked to do. For this purpose the examiner shows the patient plates 1, 2, and 3, tracing the red line, and letting him recognize that they are STAR, CIRCLE and TRIANGLE. He/She then says outloud whether it is a star, circle and triangle.
Then with plates 4, 5, and 6 the person is tested. He is asked to say that shapes they are.
The Second examination is with curved lines. First the examiner shows the examinee that he must trace the curved line. For this plate 7, 8, 9 and 10 is used. Then, when the examinee understands what he/she is to do. He/she traces plates 10. In this case care should be taken to keep the plates at a distance of more than 50-55 cm.

No. 1. Recognize as STAR by both normal and abnormal.
No. 2. Recognize as CIRCLE by both normal and abnormal.
No. 3. Recognize as TRIANGLE by both normal and abnormal.
No. 4. Recognize as STAR by normal but usually as TRIANGLE by abnormal.
No. 5. Recognize as CIRCLE by normal but usually as SQUARE by abnormal.
No. 6. Recognize as TRIANGLE by normal but usually as CIRCLE by abnormal.
No. 7. Recognized as a curved line by both the normal and abnormal.
No. 8. In tracing the winding line between upper left mark x and lower right mark x, the normal traces the upper green curve and the abnormal usually traces the lower red curve.
No. 9. In tracing the winding line between upper left mark x and lower right mark x, the normal traces the upper brown curve and the abnormal usually not recognize the line.
No. 10. Starting from the upper left mark x, the normal can trace upper and lower curve and come back to the starting mark. In case of the abnormal, some can trace either upper red line or lower red purple curve.
Where the abnormality is only slight, some patients can trace both correctly. In a very few cases the abnormal subject does not recognize either one.



Analysis of Results

1. Those who can not recognize any curve in plate 10 at all or any lower curve are definitely abnormal.
2. They might be abnormal if the misjudge more than three plates among plates 4, 5, 6, and 7.
3. If a person mistakes one or two plates among the above mentioned 5, it is better, if possible to reexamine him/her in some detail when he is better able to understand and respond. Some may trace plates 8, 9, and 10 irregularly, making the analysis difficult. In such a case, a definite diagnosis should not be made.

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies

REF	**IT** Codice prodotto **GB** Product code **FR** Code produit **DE** Erzeugniscode **ES** Código producto **PT** Código produto **GR** Κωδικός προϊόντος **PL** Numer katalogowy **RO** Cod produs **SK** Kód výrobku **LT** Gaminio kodas كود المنتج **SA**
LOT	**IT** Numero di lotto **GB** Lot number **FR** Numéro de lot **DE** Chargennummer **ES** Número de lote **PT** Número de lote **GR** Αριθμός παρτίδας **PL** Kod partii **RO** Număr de lot **SK** Číslo šarže **LT** Partijos numeris رقم الدفعة **SA**
	**IT** Conservare in luogo fresco ed asciutto **GB** Keep in a cool, dry place **FR** Á conserver dans un endroit frais et sec **DE** An einem kühlen und trockenen Ort lagern **ES** Conservar en un lugar fresco y seco **PT** Armazenar em local fresco e seco **GR** Διατηρείται σε δροσερό και στεγνό περιβάλλον **PL** Przechowywać w suchym miejscu **RO** A se păstra într-un loc răcoros şi uscat **SK** Skladujte na chladnom a suchom mieste **LT** Laikyti vėsioje, sausoje vietoje يحفظ في مكان بارد وجاف **SA**
	**IT** Conservare al riparo dalla luce solare **GB** Keep away from sunlight **FR** Á conserver à l'abri de la lumière du soleil **DE** Vor Sonneneinstrahlung geschützt lagern **ES** Conservar al amparo de la luz solar **PT** Guardar ao abrigo da luz solar **GR** Κρατήστε το μακριά από ηλιακή ακτινοβολία **PL** Przechowywać z dala od światła słonecznego **RO** A se păstra ferit de razele soarelui **SK** Skladujte mimo slnečného svetla **LT** Saugoti nuo saulės šviesos يحفظ بعيدًا عن ضوء الشمس **SA**
	**IT** Fabbricante **GB** Manufacturer **FR** Fabricant **DE** Hersteller **ES** Fabricante **PT** Fabricante **GR** Παραγωγός **PL** Producent **RO** Producător **SK** Výrobca **LT** Gamintojas الشركة المصنعة **SA**
	**IT** Data di fabbricazione **GB -** Date of manufacture **FR -** Date de fabricatio **ES -** Fecha de fabricación **PT -** Data de fabrico **DE -** Herstellungsdatum **GR -** Ημερομηνία παραγωγής **PL -** Data produkcj **RO -** Data fabricaţiei **SK -** Dátum výroby **LT -** Pagaminimo data datums **SA** - تاريخ التصنيع

MD	**IT** Dispositivo medico **GB** Medical Device **FR** Dispositif médical **DE** Medizinprodukt **ES** Producto sanitario **PT** Dispositivo médico **GR** Ιατροτεχνολογικό προϊόν **PL** Wyrób medyczny **RO** Dispozitiv medical **SK** Zdravotnícka pomôcka **LT** Medicinos priemonė جهاز طبي **SA**
CE	**IT** Dispositivo medico conforme al regolamento (UE) 2017/745 **GB** Medical Device compliant with Regulation (EU) 2017/745 **FR** Dispositif médical conforme au règlement (UE) 2017/745 **DE** Medizinprodukt im Sinne der Verordnung (EU) 2017/745 **ES** Producto sanitario conforme con el reglamento (UE) 2017/745 **PT** Dispositivo médico em conformidade com a regulamento (UE) 2017/745 **GR** Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΌΣ (ΕΕ) 2017/745 **PL** Wyrób medyczny zgodny z Rozporządzenie (UE) 2017/745 **RO** Dispozitiv medical realizat în conformitate cu prevederile regulamentul (UE) 2017/745 **SK** Zdravotnícka pomôcka v súlade s nariadením (EÚ) 2017/745 **LT** Medicinos priemonė atitinka reglamentą (ES) 2017/745 (UE) 2017/745 جهاز طبي يتوافق مع التوجيه **SA**
	**IT** Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB** Caution: read instructions (warnings) carefully **FR** Attention: lisez attentivement les instructions (avertissements) **DE** Achtung: Anweisungen (Warnungen) sorgfältig lesen **ES** Precaución: lea las instrucciones (advertencias) cuidadosamente **PT** Cuidado: leia as instruções (avisos) cuidadosamente **GR** Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις) **PL** Ostrzeżenie – Zobacz instrukcję obsługi **RO** Atenţie: Citiţi şi respectaţi cu atenţie instrucţiunile (avertismentele) de utilizare **SK** Pozor: Pozorne si prečítajte a dodržiavajte pokyny na použitie (výstrahy) **LT** Įspėjimas: atidžiai perskaitykite instrukcijas (perspėjimus) الحذر: قراءة التعليمات (التحذيرات) بعناية **SA**

	**IT** Leggere le istruzioni per l'uso **GB** Consult instructions for use **FR** Consulter les instructions d'utilisation **DE** Gebrauchsanweisung beachten **ES** Consultar las instrucciones de uso **PT** Consulte as instruções de uso **GR** Διαβάστε προσεχτικά τις οδηγίες χρήσης **PL** Przeczytaj instrukcje użytkowania **RO** Citiți instrucțiunile de utilizare **SK** Prečítajte si návod na použitie **LT** Žiūrėkite naudojimo instrukcijas **SA** اقرأ بدقة وحرص تعليمات الاستخدام
UDI	**IT -** Identificatore univoco del dispositivo **GB -** Unique device identifier **FR -** Identifiant unique de l'appareil **DE -** Unique Device Identifier (Eindeutige Kennung des Geräts **ES -** Identificador de dispositivo único **PT -** Identificador exclusivo do dispositivo **GR -** Μοναδικό αναγνωριστικό συσκευής **PL -** Unikalny identyfikator urządzenia **RO -** Identificatorul unic al dispozitivului **SK -** Jedinečný identifikátor zariadenia **LT -** Unikalus įrenginio identifikatorius **SA -** معرّف فريد للجهاز