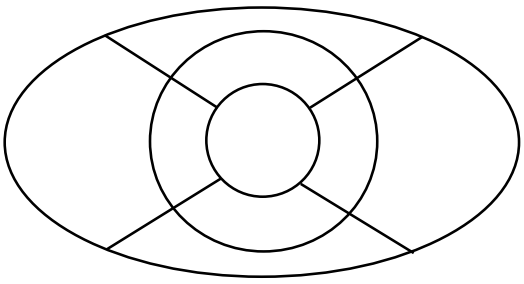
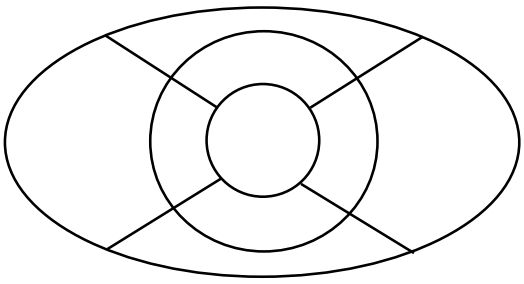
DEWS	**DRY EYE: DIAGNOSTIC TEST TEMPLATE**	
RAPPORTEUR	A.J.Bron	22nd Oct 2004
TEST	**GRADING STAINING: CLEK Schema**	
TO DIAGNOSE	The scheme is used to estimate surface damage in dry eye.	REFERENCES
VERSION of TEST	[V1]	Barr et al. 1999 [CLEK study]
DESCRIPTION	Surface damage to the exposed eye, assessed by staining, is graded against standard charts.	
NATURE of STUDY	**Nature of study** In this study, 75 patients regarded as having mild to moderate dry eye were assessed for symptoms, MGD, tear quality, meniscus height, blink quality, TBUT F and BR staining, phenol red test and Schirmer. 70.7% female. 61% using ATS 21.9% met European Criteria for moderate to severe dry eye. About 30% were CL wearers.	Nichols et al. 2004
CONDUCT of TEST	**Fluorescein instillation:** Fluorescein strip wetted with buffered saline. Drop instilled on inferior palpebral conjunctiva. Blink several times. **Rose Bengal Staining:** A Rosets™ Rose Bengal Ophthalmic Strip is wetted with sterile buffered saline and instilled on the inferior bulbar conjunctiva. ("care taken to instill adequate dye") **STAINING:** 5 corneal regions and 4 conjunctival regions as described in the CLEK study (Barr et al. 1999). The staining scale was 0-4, with 0.5 unit steps in each of the 5 corneal regions. Photos were used as examples of severity. The "total score" could either be summed, or averaged.	Nichols et al. 2004 Barr et al. 1999 [CLEK study]

OD



OS



C I N T S =Central Inferior Nasal Temporal Superior
0-4 scale in 0.5 unit steps

	circle	location	Check appropriate box				
OD	Location	Cornea/Conj.	Punctate	FB	Coalesced	Full-Thickness	Other
Stain 1	C I N T S						
Stain 2	C I N T S						
Stain 3	C I N T S						
Stain 4	C I N T S						
Stain 5	C I N T S						
Stain 6	C I N T S						
Stain 7	C I N T S						
Stain 8	C I N T S						
Stain 9	C I N T S						

RESULTS of STUDY	NA	
Web Video	Not available	
Materials:	• Barnes-Hind Ful-Glo® Fluorescein Sodium Ophthalmic strip • Rosets™ Rose Bengal Ophthalmic Strip (Chauvin Pharmaceuticals) • Source of non-preserved buffered saline.	
Standardization	Nil additional	
Diagnostic value		
Repeatability	Intra-observer agreement. **Corneal and Conjunctival Staining** **Sum of all regions**: **Fluorescein stain**: The weighted κ was: 0.69 (95% CI = 0.35, 0.81) and the intraclass correlation coefficient was 0.76 (95% CI = 0.58, 0.87). **Bengal rose stain**: The weighted κ was: 0.33 (95% CI = 0.45, 0.93) and the intraclass correlation coefficient was 0.40 (95% CI = 0.0.09, 0.64). Note that agreement was better for fluorescein than for bengal rose, perhaps because the bengal rose strip gives weaker staining than the fluorescein strip. Note too, that agreement was less good for individual zones assessed independently as follows:	Nichols et al. 2004

Unweighted κ for presence versus absence of F and BR staining. (κ values; (% agreement)				
Zone	Cornea Fluor	Cornea Bengal R	Conj Fluor	Conj Bengal R
Inf	0.18(58.7)	0.02(81.3)	0.25(70.7)	0.14(60.0)
Nas	0.23(70.7)	-0.02(94.7)	0.14(56.0)	0.09(65.3)
Temp	0.47(82.7))	0.49(97.3)	0.10(54.7)	0.46(92.0)
Sup	0.28(82.7)	N/A	0.31(90.7)	N/A
Centr	0.29(81.3)	N/A		

	<table><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td colspan="5">N/A Not available because no stain K values: 0-0.2 slight agreement; 0.21-0.40 fair agreement; 0.41-0.60 moderate agreement; 0.61-<1.0 excellent; 1.0 =perfect agreement.</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table> Note, even in region of most frequent corneal staining, $\kappa = 0.21$: It was concluded that perhaps zone scores varied between visits but the total sum of scores was more constant.	
Sensitivity	**(true positives)** [NA]	
Specificity	**(100 – false positives)** [NA]	
Test problems	About 30% were CL wearers. They do not appear to have been analyzed separately. Only a single observer was involved in the repeatability measurements. Did patients stop ATS drops before assessment?	
Test solutions	None supplied	
Glossary	CLEK- Collaborative Longitudinal Evaluation of Keratoconus	

References:

Barr JT, Schechtman KB, et al. (1999). Corneal scarring in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study: baseline prevalence and repeatability of detection. *Cornea* 18(1): 34-46.

Nichols KK, Mitchell GL, et al. (2004). The repeatability of clinical measurements of dry eye. *Cornea* 23(3): 272-85.